Polyvagal Informed Therapy for Body Awareness and Managing Emotions for People Living with Obesity: A Multiple Baseline Study

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May 2023

Research submitted in partial fulfilment of the requirements for the degree of Doctor in Clinical Psychology (DClinPsy), Royal Holloway, University of London.

Acknowledgements

First and foremost, a huge thank you to the wonderful people who took part in the study. It was such a privilege to be a part of their journey, witness their vulnerability, courage and befriend their nervous systems.

Thank you to Dr Katie Ashcroft, my academic supervisor, whose expertise in polyvagal theory and clear guidance was invaluable throughout. I have hugely benefited from her wise reflections, thoughtful supervision and ability to keep me grounded. I would also like to thank the course team for supporting me in pursuing my project and allowing my vision to become a reality.

I am thankful to all my friends for filling the gaps between studying with laughter, joy and endless social plans. Thank you to my inspiring mother, for always encouraging me to pursue my dreams and for instilling in me the values and qualities required for a clinical psychologist. To my partner for being unfailingly supportive, patient and understanding when I've needed to prioritise my studies. Thank you for your profound belief in me and reminding me - I can do it all!

Finally, special thanks to Dr Esme Banting for her unwavering enthusiasm on this subject and dedication to meeting the clinical needs of people with bigger bodies. I feel so grateful to be surrounded by such inspiring women in my life and in Esme's words, "May this just be the beginning".

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Chapter I: Lay Summary

Background

The number of people living with obesity and overweight in the UK is growing. People with obesity face considerable weight stigma which can worsen their physical and emotional health. Current treatments for this group often focus on weight despite research showing that weight loss is not maintained in the long term. In fact, research has shown that focusing on weight can impact people's psychological wellbeing and does not relate to overall health improvements.

Another area of therapeutic target is emotional wellbeing. It is well documented that people living with obesity can find it difficult to notice and cope with changes in their body that lead to the experience of emotions. This can lead to unhelpful ways of coping such as emotional eating which can contribute to difficulties. Previous research has shown that talking therapies can help people manage emotions, but these therapies often overlook an important aspect that is relevant for people in bigger bodies – the ability to trust the body. Therefore, there is a clinical need to develop interventions to support the psychological health of people living with obesity that addresses people's ability to notice, trust and cope with physical changes in their body that underpin emotional experience.

Conceptual Review

The conceptual review (CR) of the literature aimed to bring together our understanding of the bodily signals that play a role in emotional experience. The ability to sense these bodily signals is called interoception. First, the CR summarises what we know about interoception generally and the literature on interoception for people living with obesity. There is research on how interoception relates to emotions and how it relates to hunger and thirst for people living with obesity. Research suggests that factors outside the body such as weight stigma can also affect people's ability to trust the body. The CR

discusses evidence for interventions that target interoception, though these have not yet been applied to people with obesity.

Secondly, the CR discusses the literature on polyvagal theory (PVT), a way of understanding how our autonomic nervous system (ANS) works. The ANS is the system in the body that makes us feel calm, frightened, or numb. PVT explains that our ANS is responsible for responding to possible threats in our environment by triggering changes in the body to prepare us to cope with that threat. Research shows that when people have been exposed to threat repeatedly in childhood, this can cause the ANS to become hypersensitive to threat in adulthood. PVT in therapy (PVTT) supports people to understand their ANS, normalising and respecting bodily responses and provides behavioural strategies to regulate the body and cope with emotions.

The CR finally brings together the literature on these two fields to propose a model of how PVTT can be applied to understand and target interoception in people living with obesity. It then outlines important research questions that are outstanding from the literature and how these should be addressed.

Empirical Paper

The empirical paper (EP) aimed to evaluate the acceptability and effectiveness of PVTT for improving interoception and emotion regulation for people using an NHS specialist weight management service. Experts by experience (EBE) from Obesity UK were involved to review the consent form, information sheet, and co-produce some of the questionnaires.

Participants completed questionnaires daily and weekly to measure interoception, emotion regulation and they each chose a personally meaningful behaviour they currently do in response to emotions that they would like to reduce e.g., emotional eating. Participants also measured heart rate variability (HRV) daily. HRV is the variation in time between heart beats and reflects how responsive the ANS is.

Nine participants took part in the study and completed a questionnaire about adverse childhood experiences at the start to understand how their early life might have affected their ANS. Participants were randomised to one, two or three weeks of completing measures before starting PVTT. Participants completed up to six sessions of PVTT and then began a three week follow up period. At the end of the intervention, they completed a questionnaire asking how acceptable they found PVTT.

Results show significant change for four participants in improving body awareness and these changes were maintained for all those who completed follow up. Five participants demonstrated significant change in improving emotion regulation and three of these maintained or continued to improve through follow up. Five participants showed significant reductions in their chosen behaviour. All of those who completed follow up maintained treatment gains or continued to decrease their chosen behaviour.

It was found that four participants showed reliable change on both standardised measures of interoception. Most participants showed changes for attention regulation, body listening and trusting in relation to interoception. This suggests the intervention has improved people's ability to pay attention to, listen and trust their body's signals. Most participants showed no changes to their HRV. Two participants showed reduced HRV over the course of the study, which is contrary to the expected findings.

Participant feedback was very positive, with participants rating general acceptability highly. They had a positive attitude towards liking the intervention, felt that the intervention made sense and perceived it as effective.

Summary

The findings of the CR and EP provide preliminary theoretical and empirical evidence of the effectiveness of PVTT for people living with obesity to support interoception and emotion regulation. There is also evidence to suggest treatment durability as most changes

were maintained through to follow up. These encouraging results are relevant to clinicians working directly with people in specialist weight management services.

Future studies would benefit from further replication of the current findings to increase generalisability. It would also be interesting to examine the optimum number and frequency of sessions as for some people, treatment gains were realised towards the end of the intervention when there were more behavioural strategies and sessions reduced to fortnightly.

The findings from this research project have been disseminated across clinicians in the national complex case forum and intend to be written up for publication to reach a wider research audience. They will also be shared with the target population via social media platforms with the support of Obesity UK.

Chapter II: Polyvagal Theory as a Conceptual Framework to Understanding Interoception in People Living with Obesity: A Conceptual Review

Abstract

It is well evidenced that people living with obesity have deficits in interoception, the sense of one's bodily signals. Interoception involves the ability to accurately identify, trust and respond flexibly to visceral-afferent signals from the autonomic nervous system (ANS) and physiological changes in the body. Poor interoceptive abilities can lead to reliance on external means of regulation such as emotional eating which can maintain psychological and weight difficulties. This review covers two areas of research related to interoception in obesity. Firstly, it synthesises research related to interoception and the experience of emotion for people living with obesity. Secondly, it discusses literature on interoception as it relates to hunger and satiety. Polyvagal theory (PVT) offers an understanding of the ANS as our stress response. It explains how we evaluate cues of threat and safety in our environments that trigger adaptive ANS responses. PVT in therapy (PVTT) offers a novel therapeutic approach to understanding the role of interoception in the physiological and psychological interactions in emotional experiences for people living with obesity. This review discusses the theoretical grounds for evaluating the clinical applicability of PVTT for people living with obesity to target interoception and emotion regulation. Key research questions and gaps in the literature are outlined and the scientific methods to address these are discussed.

Introduction and Background

The increased prevalence of overweight and obesity in the UK is associated with a significant financial burden on the national health service (NHS) with costs projected to reach £10 billion by 2050 (Department of Health and Social Care [DHSC], 2007; NHS Digital, 2021). It is understood that such changes are not attributed to poorer willpower or individual responsibility, but a reflection of complex bio-psycho-social processes that increase the likelihood for individuals to gain and retain excess weight (DHSC, 2007). Obesity is associated with several chronic and life limiting diseases including cardiovascular disease, type 2 diabetes and cancer (World Health Organisation [WHO], 2023). Weight management interventions and public health campaigns commonly focus on reducing energy intake and increasing physical exercise (Public Health England [PHE], 2021; WHO, 2021). However, these interventions often prove ineffective for long term weight loss and can damage physical health, induce eating disorders and impact psychological wellbeing (Bacon & Aphramor, 2011; Hohman et al., 2018; Montani et al., 2015; Salas, 2015). This raises ethical implications and highlights the importance of the development of novel interventions to support people with obesity that focus on health promotion rather than weight loss (Bacon & Aphramor, 2011; Hunger et al., 2020). One non-weight related area for therapeutic target is emotion regulation (ER) as people living with obesity commonly have difficulties with regulating emotions (Fernandes et al., 2018; Robinson et al., 2021). This can lead to unhelpful coping mechanisms such as excessive eating in response to emotions (van Strien et al., 2018). This is known as emotional eating (EE) and is well evidenced within this population to contribute to weight and psychological difficulties (Konttinen et al., 2019; van Strien, 2018).

One explanation of poor ER is that people have become disconnected from their bodily signals (Damasio, 2010; Craig, 2015). These include noticing your heart beat faster,

temperature changes and feeling hungry. The ability to sense these internal signals in the body is known as interoception (Khalsa et al., 2018). Meta-analyses have evidenced poor interoception in people living with obesity (Robinson et al., 2021). Interoceptive sensations are thought to be the basis of emotional feelings (Damasio, 2010; Craig, 2015; Wiens, 2005) and poor interoception has been linked to EE, binge eating, loss of control eating and weight gain (Young et al., 2017; Zijlstra et al., 2012).

Difficulties in ER and interoception are well documented in obese populations and therefore, have been posited as a target for psychotherapeutic care (Robinson et al., 2021; Willem at el., 2019). Several experimental studies have demonstrated the effectiveness of ER interventions in regulating obesity and food intake (O'Reilly et al., 2014) yet these interventions overlook the role of interoception in emotional experience. Elsewhere, training interventions have shown to improve interoception for healthy samples (Bornemann et al., 2015) though to the authors knowledge these have not been applied to obese populations. Specifically, ER therapies overlook the importance of trust in bodily signals, a critical facet of interoception for people living with obesity (Willem et al., 2019, 2021).

Polyvagal theory informed therapies (PVTT) are psychological interventions that draw on polyvagal theory (PVT; Porges, 1995) of the autonomic nervous system (ANS) to support people increase awareness (interoception) of their physiological responses (Porges & Dana, 2018). PVTT supports non-judgemental acknowledgment and respect for physiological shifts as these are normalised in the context of how our body works in response to stress and threats. This increased awareness supports ER as when people can tune into and understand physiological changes, they are afforded more choice over their behavioural response (Dana, 2018).

PVTT offers a theoretically plausible framework to support people with obesity to notice and understand their bodily signals, learn to trust these sensations and adaptively

regulate. There is currently no literature synthesising these fields. Therefore, this conceptual review will assimilate and evaluate the literature to date on interoception in people living with obesity and the use of PVTT. A novel model of PVT as a conceptual framework to understanding and targeting interoception in people living with obesity will be proposed that integrates the research presented throughout this review. Finally, key research questions for future research are noted alongside the proposed methodologies to address these.

Emotion Regulation in People Living with Obesity

Individuals employ a number of conscious and unconscious mental and behavioural strategies to regulate their emotional state, experience and to influence psychological outcome (Aldao et al., 2010; Gross et al., 1998). This is of particular relevance to western societies, where control over emotions is heralded as a valued trait (Gross et al., 1998). On one hand, adaptive ER is related to effective executive control and improved social performance (Teper et al., 2013; van't Wout et al., 2010). On the other hand, poor ER is associated with psychological ill health including worry, anxiety and problem behaviours such as gambling (Salters-Pedneault et al., 2006; Williams et al., 2012). The use of certain ER strategies can be more or less adaptive in terms of their association with psychopathology (Aldao et al., 2010). For example, reappraisal and problem solving are more adaptive compared to rumination and suppression which are associated with anxiety, depression and eating disorders (Aldao et al., 2010). This suggests a certain transdiagnostic nature to ER which is relevant to obese populations who can present with a range of comorbid psychological disorders (Weiss et al., 2020). ER can contribute to body dissatisfaction and disordered eating as people living with obesity who struggle to identify and adaptively cope with emotional states commonly turn to external means of regulation, namely food (Fernandes et al., 2018; Konniten et al., 2010).

In a review and meta-analysis by Fernandes et al. (2018), they reported more expressive suppression in those with obesity compared to controls. They explain expressive suppression is indicative of an emotionally avoidant style and that this affects one's ability to identify and acknowledge emotions, leading to poor ER. Weiss et al. (2020) support this idea in their review which reports evidence for difficulties with emotion acknowledgement and regulation for people with obesity. Weiss et al. (2020) focuses on the relationship flowing from psychopathology to obesity in adults. Developmentally, poor ER in children has been positioned alongside stress as a risk factor for obesity and therefore important in preventative interventions (Aparicio et al., 2016). However, there is also an understanding that living with obesity negatively impacts ER as a result of living with a long-term condition (Wierenga et al., 2017). This is due to the chronic emotional demands placed on those with long term conditions which can drain their emotional resources and therefore ability to emotionally regulate effectively. Demographic risk factors of being young, female, increased negative affect, lower educational attainment and non-white are significant for ER difficulties for those with long term conditions such as obesity (Wierenga et al., 2017). The risk factor of increased negative affect is of importance given the increased reporting of negative affect in people with obesity (Ziljstra et al., 2012). Unfortunately, Wierenga et al.'s (2017) paper combined multiple ethnicities into one 'non-white' category which overlooks further specificity.

Overall, this research evidences the complexity in the bi-directional relationship between ER and obesity. Of importance to the proposed model in this review, Weirenga at al., (2017) provides evidence for the positive association between weight and body size and emotion dysregulation such that those in bigger bodies tend to have increased difficulties with ER. This also highlights the influence of external and societal factors which are addressed later in the review.

Interoception

Interoception is defined as a one's sense of internal bodily signals from heart rate, hunger, fullness, to temperature (Garfinkel et al., 2015). Of relevance to this review, it is thought to be the basis of emotional experience (Critchley & Garkinkel, 2017; Wiens, 2005). Naturally, accurate detection of these bodily signals is vital for their regulation (Garfinkel et al., 2015). Garfinkel et al. (2015) propose three types of interoception: interoceptive accuracy, sensibility, and awareness. Interoceptive accuracy refers to an individual's ability to accurately detect internal bodily signals and is measured through comparison to objective measures such as heart rate monitors. Interoceptive accuracy has been used in the literature interchangeably with the term interoceptive sensitivity (Murphy et al., 2017). For the purposes of this review, the term interoceptive accuracy will be used.

Measurement of interoceptive accuracy usually takes the form of the heartbeat counting or detection task. In the first instance, participants are asked to count their heartbeat and this is then compared to an objective measure of their actual heartbeat (Ring & Brener, 2018). In the latter, participants hear tones related to their electrocardiogram (ECG) and are asked to report whether they think they accurately coincide with their own heartbeat (Kleckner et al., 2015). High concordance indicates high interoceptive accuracy. Whilst reliability of these types of tasks are well established and they provide a relatively simple and unintrusive tool, these methods have raised concerns about validity and the suitability for research (Brener & Ring, 2016; Ring & Brener, 2018). Specifically, there is little intra-task correlation between these two methods suggesting they are measuring distinct processes (Ring & Brener, 2018). Furthermore, these tasks lack sensitivity for low ability levels with evidence that a large proportion of healthy individuals have difficulties assessing heart rate at rest (Khalsa et al., 2009), some rely on guessing (Wiens, 2005) and some rely on vibrations on the chest wall (Khalsa et al., 2009). The latter can be hugely impacted by bodily

differences, such as percentage of body fat (Rouse et al., 1988) which is relevant for assessing interoception in an obese population. Furthermore, heartbeat counting and discrimination tasks may not accurately capture the complex interplay between bodily signals and subjective experience. Whilst they may serve to ascertain interoceptive ability related to basic science questions, they overlook what is clinically important in interoceptive ability and the depth of idiographic interoceptive experience (Bornemannn et al., 2015; Khalsa et al., 2009; Parkin et al., 2014).

Interoceptive sensibility refers to an individual's subjective reporting of tuning into their bodily signals, a self-reported interoception (Garfinkel et al., 2015). This is usually assessed through self-report measures such as the multidimensional assessment of interoceptive awareness (MAIA) questionnaire (Mehling et al., 2012). Whilst there are obvious issues with social desirability bias in self-report measures, they allow a broader measurement of interoceptive awareness as they also capture related beliefs, attitudes and emotions (Bornemann et al., 2015). The MAIA has been critiqued for asking participants to report on 'general daily life'. The lack of specification in terms of time frame can compromise the ecological validity and be subject to memory bias (Ebner-Priemer & Trull, 2009). Other questionnaires include the body perception questionnaire (BPQ; Porges, 1993) and the body awareness questionnaire (BAQ; Shields et al., 1989), however these do not include the regulatory features of interoception (Mehling, 2016; Mehling et al., 2009). MAIA is most commonly used, and this has since been developed into a second version, MAIA-2 which improves on previous shortcomings in relation to internal consistency on not-worrying and not-distracting scales. These correspond to the tendency to feel distress in relation to pain or discomfort and the tendency to disregard or distract from pain or discomfort respectively (Mehling et al., 2018).

Interoceptive awareness is the correspondence between accuracy and sensibility in that it refers to a metacognitive level of interoception (Garfinkel et al., 2015). For interoceptive awareness, an individual is not only able to accurately detect internal bodily signals but has a level of confidence in their ability to do so. Finally, interoceptive ability is the capability to coordinate these three facets of interoception, an umbrella term capturing all aspects of interoception. Garfinkel et al. (2015) proposes the three facets are distinct since they demonstrated that interoceptive awareness and sensibility could not fully predict interoceptive accuracy. The lack of association between interoceptive accuracy and self-report measures has been used as evidence to further support the notion of distinctness of these facets (Calì et al., 2015; Ceunen et al., 2013; Garfinkel et al., 2015).

Garfinkel et al.'s (2015) proposal has been critiqued for overlooking implicit interoception, which is the subconscious perception of internal states (Murphy et al., 2017). Other theorists define interoception as the sensed interactional processes across conscious and unconscious levels (Feinstein et al., 2018). Murphy et al. (2017) outline interoceptive ability as a product of four components. First there is the bodily signal itself and how 'loud' this is for the individual. Secondly, there is transmission of this signal to the central nervous system which leads to the third component – the unconscious perception of interoceptive states, sometimes referred to as implicit interoception. Fourth and finally there is the conscious perception, recognition and ability to differentiate interoceptive signals explicitly (Murphy et al., 2017). The conceptualisation of interoception into these four stages provides a more comprehensive understanding as it is grounded in a developmental understanding of interoception. Further it suggests that difficulties can occur at any one of these stages giving rise to individual differences in interoceptive ability (Murphy et al., 2017).

Challenges in clear definitions of interoception can be attributed to the lack of consensus on the characterisation of interoception and measurement variations. As mentioned

earlier, terms such as interoceptive sensitivity and accuracy are used interchangeably in the literature. Further complications can arise because interoceptive abilities vary in relation to the type of sensation (Ferentzi et al., 2018; Forrest & Smith, 2021; Khalsa et al., 2018). This means that an individual's ability to accurately perceive heartbeat may vary from detecting gastric sensations. This is of relevance to people living with obesity since gastric sensations may be misascribed as emotional state changes (van Strien, 2018). However, despite divergent findings in relation to differing facets of interoception and methods of measurement, there is a consensus that interoception is unequivocally linked to atypical and typical psychological processes and emotional experience and warrants clinical research attention (Craig, 2015; Garfinkel et al., 2022; Murphy et al., 2017).

Interoception and Emotional Experience in Obesity

A recent meta-analysis of 87 studies by Robinson et al. (2021) established poorer interoception in those with overweight and obesity compared to normal weight individuals in cross-sectional studies. They found no moderation effects for the facets of interoception on the association between high BMI and deficits in interoception. Robinson et al. (2021) propose that more research is required to understand the links between interoceptive accuracy and sensibility and suggest that, although distinct, both are needed for adaptive functioning. This idea is supported by Willem et al. (2021) who seconds the notion that it is the combination of detection and trust in these cues that support healthy functioning. However, Willem et al. (2021) differentiate their theoretical stance from Robinson et al. (2021) in that they delineate interoceptive sensibility further. They propose that interoceptive sensibility can be broken down into awareness and reliance. According to Willem et al. (2021), low interoceptive awareness is linked to emotional dysregulation in people with obesity and this relationship can be explained by interoceptive reliance. They propose a directional relationship in that an individual first must accurately notice the cues, then be able to trust

and rely on these cues. This is different to Garfinkel et al.'s (2015) definition of awareness as Willem describes it as part of sensibility and subjective reporting rather than metacognition. This has implications for therapeutic interventions which should focus on supporting individuals not only with the ability to attend to their bodies, but also be able to trust, effectively cope with and manage what they notice (Willem et al., 2021).

This highlights developments in the interoceptive literature that explain interoception as not only a 'bottom up' process of gathering information from the body but that 'top down' interoceptive inferences are central to overall ability (Young et al., 2017). In this, emotional experience is a result of 'top down' interpretation of the causes of 'bottom up' signals (Seth, 2013). These inferences and meanings attributed to bodily signals are influenced by past experiences which shape the 'top down' process (Young et al., 2017). The extent to which 'top down' versus 'bottom up' processes are relied on depends on how much trust the individual has in each (Feldman & Friston, 2010). Paulus and Stein (2010) propose that interoceptive signals are associated with self-referential beliefs that, over time, generate interoceptive schemas. In their paper they describe how bodily sensations such as increasing heart rate can trigger beliefs such as "I can't breathe" which can lead to activation of the sympathetic fight/flight response. This sympathetic nervous system (SNS) activation can lead to maladaptive behaviours of avoidance (Paulus & Stein, 2010). This can be explained by difficulties with differentiating between normal afferent changes in the body and those which indicate something more serious. This highlights the cognitive contribution to interoceptive ability. As there is evidence of increased interoceptive awareness for some people with obesity (Young et al., 2017), it could be that a heightened awareness of the body, without the ability to trust the body (Willem et al., 2021) triggers maladaptive threat schemas that lead to unhelpful ways of coping, such as emotional suppression (Fernandes et al., 2018).

Beliefs about bodily signals are learnt from the environment and past experiences of interoceptive signals (Paulus & Stein, 2010). The linking of 'bottom up' interoceptive signals to belief-based processes is important to consider, especially in light of the increased negative thoughts one can have about their body when living with obesity (Zijlstra et al. 2012). Whilst this suggests being in a bigger body can affect interoception, there is evidence that interoception may also contribute to the development of one's body image (Badoud & Tsakiris, 2017). Body image is the thoughts, feelings and beliefs one holds about their body and feeds into personal identity (Cash, 2004). Badoud and Tsakiris (2017) propose that poor interoception can lead to difficulties with body image and therefore position it as a key target for interventions. Based on neuroimaging and experimental studies, they propose a directional relationship in which poor interoception predisposes an individual to have greater body image dissatisfaction. This relationship is supported by Todd et al. (2019) who found strong associations between interoception and body image. In particular, they highlighted the significant contribution of the MAIA trusting subscale as the most important facet of interoception for understanding positive body image. With this evidence, Todd et al. (2019) advocate for trust in bodily signals to be a target for clinical work. However, given the cross-sectional nature of this research, further empirical work is needed to establish causal hypotheses.

Badoud and Tsakiris (2017) point to a general limitation of research into interoception in people living with obesity. As aberrant interoception is commonly associated with psychopathologies such as anxiety and panic (Domschke et al., 2010), depression (Dunn et al., 2007) and attention deficit hyperactivity disorder (ADHD; Kutscheidt et al., 2019), delineating the contribution of interoception to ER or body image issues alone is challenging (Badoud & Tsakiris, 2017). This highlights a wider tension in research, the desire to understand a phenomenon through the investigation of its parts which can lead to

reductionism. This is of particular relevance to an obese population, a heterogenous group characterised not only by their weight but also a high number of associated comorbid psychopathologies (Weiss et al., 2020).

In relation to specific interoceptive facets, Young et al. (2017) found a positive association between interoceptive accuracy and EE. They explained that this indicates high emotional arousal which could explain that emotions are felt more intensely in this population leading to difficulty regulating. They found that although EE was associated with increased interoceptive accuracy, there was a reduced interoceptive awareness and this was not accounted for by individual differences in mood. This provides evidence to support the idea of interoceptive inference (Seth, 2013) and that there is a mismatch between reliance on 'bottom up' signals and 'top down' inferences. Young et al. (2017) findings confirm Garfinkel et al.'s (2015) study in evidencing the multifaceted, yet separate processes underlying interoception. Further, it validates Murphy et al.'s (2017) four stages as distinct and the idea that dysfunction can occur at any stage.

In sum, whilst there is a lack of consensus on the temporal relationship between interoception, obesity and ER, there is clear evidence of the associations between these factors and their potential as therapeutic targets. The literature suggests the importance of considering both 'bottom up' signals and the 'top down' processing of these signals. In support of Murphy et al., (2017) there is evidence of atypical interoception at different stages with some authors reporting high interoceptive accuracy as a precursor to poor ER (Young et al., 2017) and other authors suggesting that overall low interoceptive abilities and poor identification of emotions leads to poor ER (Robinson et al., 2021; van Strien, 2018). Whilst there seems to be conflicting evidence for high vs. low levels of interoceptive accuracy in this population, there is clear evidence for the relationship between aberrant interoceptive accuracy, poor interoceptive reliance (the ability to trust these signals) and poor ER which

leads to behaviours such as emotional eating. This speaks to the complexity of interoception, its multiple facets and the individual differences in interoceptive ability.

Interoception and its Relation to Hunger and Satiety in Obesity

In other populations, research in interoception focuses on the relationship between interoception and emotional experience. In obese populations there has been an increased focus on the role of interoception in relation to hunger and satiety. This is based on the idea that misattribution and misinterpretation of physiological changes in the body have important consequences for eating behaviours in people living with obesity (van Strien, 2018). Interoceptive accuracy and sensibility is positively associated with adaptive behaviour regulation as regulating one's self in line with bodily and environmental demands supports positive health (Füstös et al., 2013). This extends to eating behaviours, which when working adaptively support a balance between physiological energy needs and food intake (Herbert, 2020). In this, an individual experiences a hunger signal. If this is accurately detected, interpreted and trusted, the individual initiates eating. Once the physiological energy needs are met, the body signals satiation. Upon accurate detection, interpretation and trust of this signal, the eating behaviour is stopped (Herbert, 2020). However, the complex interplay of past experience and initiation of schemas can interrupt this process.

Paulus and Stein's (2010) ideas could be translatable to hunger and satiety signals. For example, a hunger signal may initiate a 'my body needs food' schema or 'threat to my diet' schema. In each of these schemas, different behaviours around food consumption could be initiated and could serve to explain the extent to which an individual 'listens' and 'trusts' the physiological signals. Consideration of beliefs about the body and the impact of diet culture are important when considering the fact that attempts to lose weight through diet plans is increasing (Han et al., 2019). Diets provide individuals with prescribed strict guidelines about what to eat and when to eat and therefore negate an individual tuning into

their bodily cues. People who have engaged in diets in an effort to lose weight, will have spent much time ignoring biological cues from the body concerning hunger and fullness. Instead, they may have focused on diet rules to dictate their eating patterns e.g., fasting for long periods of time, eating at specific times and cutting out food groups. Some theorists suggest that ignoring bodily cues over periods of time leads to a dampening of hunger cues from the body and also creates a level of distrust between the psychological mind and biological messages (Tribole & Resch, 2020). The dampening of cues aligns with Murphy et al.'s (2017) first implicit interoception stage on how 'loud' the signal is.

According to the boundary model for the regulation of eating (Herman & Polivy, 1983), dieters cognitively dismiss their biological cues so that they either only notice extreme hunger and fullness or do not notice this type of signal at all. When there are limited clear hunger or satiety cues, Herman and Polivy call this the zone of 'biological indifference'. As this zone has become so familiar for chronic dieters, individuals rely solely on external cues to inform eating behaviours, namely adhering to further diet plans. There is substantial evidence to demonstrate that dieting is linked to disordered eating and subsequent weight gain (Hetherington, 2000; Jacquet et al., 2020; Langeveld & DeVries, 2015; Siahpush et al., 2015). This could be explained by the role of interoception in the relationship between dieting and weight gain, though has yet to be directly tested empirically. Overall, this serves to highlight the role of societal informed beliefs about eating and the body in interoception for people living with obesity.

In laboratory settings, short-term food deprivation has shown to increase attunement with heartbeat (i.e., increased interoceptive accuracy), with authors concluding that diets can impact individuals by leading to a hypersensitivity to hunger cues (Herbert et al., 2012). This hypersensitivity to hunger can cause and maintain overeating and excessive weight gain. This links to the idea that increased attention on bodily signals can lead to hypervigilance and

anxiety (Paulus & Stein, 2006). Alongside this, other authors suggest that poor interoceptive abilities lead to cues of satiety being disregarded when making decisions around eating (Martin et al., 2019). This combination of increased emphasis on hunger and decreased emphasis on satiety can maintain difficulties with weight (Herbert et al., 2020). Interestingly, diminished interoceptive sensibility in relation to satiety is most evident when consuming high fat high sugar foods (Attuquayefio et al., 2017). Attuquayefio et al. (2017) found that participants showed hyposensitivity to bodily signals due to the food type. This means people were less tuned into feeling full when eating highly palatable foods. This is interesting given the tendency of EE to occur with highly palatable, high fat, high sugar foods that contribute to increased weight gain (Fuente González et al., 2022).

This presents a complex picture of the relationship between hunger, fullness cues and food types that can have hypo and hypersensitivity in relation to satiety and hunger cues. Many studies to date that look at interoception in people with obesity focus on static measurements of interoception. This means they focus on in the moment measures at one time point rather than dynamic measures of interoception or how one perceives bodily changes over time (Robinson et al., 2021). This overlooks what may be an important perspective on interoception in relation to signals of appetite which are more dynamic in nature, such as the stomach expanding in response to food (Robinson et al., 2021). Furthermore, these laboratory-based studies may not provide ecological validity which is necessary for the development of clinical interventions. This calls for the naturalistic study of interoception and how it changes over time.

Emotional Eating

Whilst presented in this paper as two strands separating interoception and its relation to emotions from its relation to hunger and satiety, there is overlap between these concepts and it is often the misattribution of emotions as hunger signals that presents as the main

difficulty for people living with obesity (van Strien et al., 2018). When there is aberrant interoceptive abilities, whether this be heightened interoceptive accuracy (Young et al., 2017) or overall poor interoceptive abilities in this population (Robinson et al., 2021), this affects the ability to emotionally regulate which is the precursor to the most commonly used and problematic ER strategy – EE (Vasileiou & Abbott, 2023).

In people living with obesity, deficits in ER can lead to eating as a form of down regulation of unwanted emotions to provide relief (Leehr et al., 2015). EE has been evidenced in response to both positive and negative emotions (Reichenberger et al., 2020). Investigation of eating in response to specific emotions has found that eating in response to depression, anger and boredom are significantly associated with poorer psychological wellbeing, symptoms of eating disorders and poor ER (Braden et al., 2018). In particular, eating in response to depression showed the strongest associations. This is in comparison to eating in response to positive emotions, which was not associated with psychological wellbeing, symptoms of eating disorders or poor ER. This contradicts previous findings in which eating in response to positive emotions was associated with symptoms of disordered eating, just to a lesser extent (Sultson et al., 2017). This discrepancy could be explained by the differing samples, in that Sultson et al. recruited from a general population and Braden et al.'s sample was overweight or obese. This suggests that eating in response to negative emotions is most relevant as a therapeutic target for obese populations.

Rather than the emotion itself, affect regulation models suggest that EE is the outcome of poor ER (Wiser & Telch, 1999). In particular, increased EE frequency is associated with lack of access to ER strategies and lack of emotional clarity (Gianini et al., 2013). Whilst this cross-sectional data precludes causal inferences, it highlights the importance of being able to identify emotions within this group and the ability to access adaptive ER strategies to overcome reliance on EE that contributes to weight gain (Gianini et

al., 2013). The association between ER ability and access to ER strategies is supported by Fernandes et al. (2018) who also evidenced limited access to ER strategies in this population which leads to over-reliance on EE.

A series of laboratory based experimental studies addressed the question of the impact of ER strategies. Evers et al. (2010) demonstrated that when participants were instructed to employ certain ER techniques their food intake was affected. This is compared to the manipulation of triggering emotional states which did not have a direct effect. Specifically, the maladaptive ER strategy of emotional suppression was responsible for the increased intake of comfort foods, rather than the emotion itself. This has been extended by Taut et al. (2012) who investigated whether one eats and how much one eats, by examining food intake in a free eating setting. Participants were instructed to use certain ER strategies including suppression and reappraisal following film clips that elicited negative emotional states. They found that the amount of food eaten did not differ between groups based on ER strategy but that those who used reappraisal were less likely to commence eating. This suggests it is the ER strategy and the way an individual copes with the negative emotions which is most relevant in explaining the occurrence of EE. Whilst critically, this may not represent naturalistic ER and EE, it is important to consider given the prevalence of emotional suppression in this population (Fernandes et al., 2018).

Overall, the research into ER for people with obesity highlights the relationships between ER, access to ER strategies (Fernandes et al., 2018; Gianini et al., 2013) and over reliance on EE which leads to weight gain (Fuente González et al., 2022). These are all relevant factors in the development of a model for understanding interoception in this population. Further, this provides two possible areas for therapeutic target: identification of emotional states through improving interoception and increasing the availability of ER strategy choice.

Weight Stigma

Given the evidence for the influence of 'top down' processes on interoceptive ability (Paulus & Stein, 2010; Seth, 2013), it is important to consider the societal factors that influence cognitive and emotional experiences for people living with obesity. Weight stigma is experienced by over half of people engaging in weight management programmes (Puhl et al., 2021). Weight stigma is the devaluation and discrimination of a person due to their weight which evokes negative stereotypes such as laziness, and unfair treatment including denial of employment (Pearl et al., 2019; Puhl et al., 2008, 2020). Interestingly, whilst there have been societal improvements in implicit bias and attitudes towards other discriminated identities including race and sexual orientation, weight bias has remained static in the period examined between 2007-2016 (Charlesworth & Banaji, 2019). Arguably this extends to the current day as a result of harmful discussion of obesity in the media and public health campaigns throughout the pandemic (Pearl & Schulte, 2021). The insidious nature of weight bias even extends to professionals working in the field of weight management. A recent study found that over half of healthcare professionals attending a webinar on non-weight focused approaches within bariatric services had an implicit weight bias against people living with overweight and obesity (Abbott et al., 2023).

Observational studies indicate the direct relationship between the experience of weight discrimination and physiological stress on the body (Jackson et al., 2016, 2017). Jackson et al. (2016) reported associations between weight discrimination and elevated levels of cortisol, an indicator of stress exposure, especially for those with severe obesity. Furthermore, perceived weight discrimination has been evidenced to mediate the relationship between obesity and cortisol levels (Jackson et al., 2017).

This has been tested in experimental studies which have shown that manipulating exposure to weight stigma increases cortisol reactivity (Himmelstein et al., 2015). This

supports cross-sectional evidence though lacks ecological validity due to its unnaturalistic setting. A 10 year prospective study, found that exposure to weight discrimination increased risk of allostatic load, the cumulative adverse consequences of stress on the body, two times (Vadiveloo & Mattei, 2017). This prospective study design allows for directional and temporal relationships to be established between these factors. These significant findings were maintained after controlling for BMI, socioeconomic status and other forms of discrimination. This strongly presents the case for the detrimental effects of weight stigma and the associated physiological impact of stress.

This is of particular interest, when considered alongside the notion that chronic high allostatic load can lead to dysfunctions of the physiological stress response, namely ANS functioning (Puhl et al., 2020). Increased physiological stress and ANS dysregulation can lead to psychological distress, EE, poorer food choices and increased food intake (Jackson et al., 2015). This highlights a perpetuating cycle such that being in a bigger body means people experience weight stigma. This stigma puts chronic pressure on their physiology, impairing ANS functioning. Poor ANS functioning affects interoceptive ability which underpins emotional experience (Jackson et al., 2015; Khalsa et al., 2018; Puhl et al., 2020). This affects ER which can impact eating behaviours which serve to maintain or worsen difficulties with weight, feeding back into weight stigma (Puhl et al., 2020). These factors and the perpetuating cycles must be considered in the development of a model to understand the role of weight stigma in interoception for people living with obesity. Furthermore, given the intersectionality of discrimination, there is increased risk for certain groups such as women where weight stigma is more prevalent (Himmelstein et al., 2015).

The impact of weight stigma and stress on the body, is of relevance given the links between interoception and stress. Schulz & Vögele (2015) propose a positive feedback model in which early life, chronic and acute stressors influence dysregulation of physiological stress

axes. For chronic stress, they argue that this can lead to excessive or enduring activation of axes such as the hypothalamic-pituitary-adrenocortical (HPA) axis and ANS. This alters homeostasis in these pathways which can permanently alter interoception. In their model, they suggest that this can increase attention and alter perception of physical symptoms which in and of themselves causes more stress, perpetuating the cycle. This provides further evidence of the relationship between ANS, interoception and ER which is of relevance to the development of a novel model. This can be understood alongside the literature on increasing interoceptive awareness leading to psychological distress if there is not support or ability to understand and trust bodily signals (Cali et al., 2015), especially for those with obesity (Willem et al., 2019, 2021).

Despite the considerable impact of weight stigma on health outcomes, there is little empirical work into the role of weight stigma in weight management programmes or interventions to support this population (Puhl et al., 2020). Attempts are being made for a paradigm shift away from weight loss, towards health promotion which embodies a weight inclusive approach (Hunger et al., 2020; Webb & Harding, 2016). A review comparing weight-normative approaches and weight-inclusive approaches found the former leads to weight regain, weight cycling, adverse health and well-being costs and contributes to perpetuating societal weight stigma (Tylka et al., 2014). This is compared to weight-inclusive approaches which uphold ethical standards of nonmaleficence and beneficence. This is supported by more recent papers which use empirical work to highlight the limitations of weight focused approaches that synonymise weight and health and overlook the impact of weight stigma (Hunger et al., 2020).

Progressive moves towards a weight inclusive approach are being adopted in research. For example, Warschburger et al.'s (2022) study protocol (empirical study yet to be published) explicitly states its position in tackling anti-fat biases by moving away from

weight-related outcomes, and instead focusing on health promoting behaviours. This prospective study aims to measure and target adaptive eating behaviours and interoceptive sensibility. This further exemplifies the importance of developing weight inclusive approaches to support people living with obesity as it recognises the potential impact an intervention can have by targeting one factor in the interactional system of factors that contribute to difficulties for people living with obesity.

Interoception as a Target for Therapeutic Interventions

As outlined above, interoceptive ability is understood to underpin emotional experience and specifically in people living with obesity can lead to dysfunctional ER, EE and contribute to weight gain. Therefore, research and clinical interest has grown in relation to targeting interoception (Khoury et al., 2018; Robinson et al., 2021; Willem et al., 2021). Interventions that modulate interoception are based on the idea that conscious cognitive and emotional control networks exert top-down regulation of physiological processes and can improve meaning making of such signals (Weng et al., 2021). There has been debate in the field as to whether interoception is best understood as a trait or state and therefore the extent to which it can be manipulated (Höller et al., 2021). Evidence from Wittkamp et al. (2018) suggests that 40% of variance in one measure of interoceptive accuracy could be explained by trait, compared to 27% explained by state. The utilisation of mindfulness based training has shown that daily practices of paying attention to the body and breath can improve interoceptive awareness, sensibility (Bornemann et al., 2015) and accuracy (Fischer et al., 2017). This implies a temporal variability and thus the applicability of training methods and modification of interoception through 'top down' processes (Höller et al., 2021; Weng et al., 2021).

Interventions that target interoception usually focus on the training of mindfulness related skills due to the understanding that interoceptive awareness underpins contemplative

practices (Hölzel et al., 2011). A positive relationship between interoceptive ability and meditation experience has been documented (Mehling et al., 2014). However, due to the cross-sectional nature of this study, a biased sample of people with lower back pain and the variability in meditative practices, causality and generalisation from this study is limited. Building on this, Bornemann et al. (2015) investigated the longitudinal effect of mental training on interoceptive sensibility, as measured by the MAIA. The three-month intervention included practices such as body scans and breath meditations which aim to foster awareness of mind-body connections. Compared to a control group, they found improvements on five out of the eight aspects of interoceptive awareness captured by MAIA. These included attention regulation, emotional awareness, self-regulation, body listening and body trusting. The use of a control group overcomes arguments that the mere completion of interoception measures over time may cause a practice effect (Höller et al., 2021). They found that changes in aspects of interoception were related to mindfulness factors as measured by the five-factor mindfulness questionnaire (FFMQ; Baer et al., 2008). This study provides empirical evidence for the idea that interoceptive awareness can be improved through intervention for non-clinical samples. These findings are supported by an eight week body scan intervention that found improvements to interoceptive accuracy as measured by the heartbeat perception task (Fischer et al., 2017). However, Fischer et al., (2017) did not find differences in interoceptive sensibility which they attributed to poor measurement tools as they used the eating disorders inventory-2 (EDI-2) interoceptive awareness subscale (Garner, 1991). Bornemann et al. (2015) attribute improvements on the trusting subscale to be as a result of paying attention to bodily sensations in a safe environment so that such sensations are experienced as cues of safety from the body. They stipulate that this may be enhanced by experiencing these bodily sensations when one is in good health due to the healthy weight sample which Fischer et al.

(2017) also recruited in their study. Therefore, the extent to which these findings can be generalised to people living with obesity is yet to be tested.

A recent review of interoception interventions highlighted the role of cognitive and behavioural techniques to target interoceptive ability (Weng et al., 2021). Through the behavioural manipulation of breathing, this can stimulate the parasympathetic nervous system (PNS) branch of the ANS, regulating SNS branch activity (Weng et al., 2021). Combined with the cognitive skills of attention without judgement, this affords improved interoceptive awareness. This has been substantiated by neuroimaging studies which have shown mindfulness training to increase insula activity, the neural underpinnings of interoception (Farb et al., 2013). It has been posited that these interventions target neuromodulation of the vagus nerve of the ANS through the combination of behavioural techniques (slow breathing) and psychological techniques (mindfulness-based therapies; Weng et al., 2021).

This work been extended for the use of mindfulness-based interventions that target interoception in obesity. Thomas et al. (2019) tested the addition of a mindfulness programme alongside an exercise and nutrition programme for cancer survivors with obesity. The theoretical underpinning of their intervention was twofold. Firstly, it is based on the idea that obesity is driven by appetite dysregulation in brain reward systems. This means that due to the consumption of highly palatable and calorie-dense foods, these overstimulate reward pathways in the brain which drive an addictive quality, disrupting natural allostatic processes in relation to food. Specifically, that people with obesity have increased attentional bias towards food cues and reduced sensitivity towards non-food related rewards. Secondly, they propose this is compounded by dysfunctional interoceptive awareness that inhibits detection of satiety. Therefore, their intervention targeted appetite dysregulation and interoceptive awareness through attentional control, cognitive reappraisal and savouring skills. They found significant changes in the mindfulness adjunct intervention group compared to the standard

programme for noticing, attention regulation, self-regulation and body listening. This provides evidence of change to the regulatory aspects of interoception in line with Bornemann et al.'s (2015) findings. Although Thomas et al. (2019) found a significant effect for time on the trust subscale, this was not significantly different between groups over time. This suggests that the adjunct of mindfulness skills did not significantly improve trust. The authors do not explain the variation in findings related to the different aspects of interoception, despite the facet of trust in obesity garnering research focus elsewhere (Willem et al., 2019, 2021). It could be that the safety of a therapeutic environment (present across both conditions) served to foster the trust component rather than specific aspects of the intervention itself, though further investigation of therapeutic components would be required to disentangle the mechanism of change. Thomas et al. (2019) did not find any evidence for weight loss as a result of the intervention, despite it being one of the primary outcomes. Noting this as a primary outcome highlights the weight centric bias in research, reinforcing a narrative of weight being unequivocally linked to health and arguably contributes to reinforcing societal anti-fat biases. The study did not measure any health-related outcomes, further conflating weight with health.

The wider application of mindfulness-based interventions to people with obesity is well documented in reviews and meta-analyses to have beneficial effects on weight and psychological outcomes (Lyzwinski et al., 2018; Ruffault et al., 2017). However, these studies do not specifically speak to the role of interoception, nor do they target this as a specific outcome. This calls for more research that directly measures interoception for the development of novel interventions (Nord & Garfinkel, 2022). Nord and Garfinkel (2022) advocate for tailored interventions that identify and target specific facets of interoception for individuals to support a precision medicine approach. This would be beneficial for people with obesity, given the heterogeneity in this group.

Despite initial promising evidence into the modifiable nature of interoception and its role in obesity, there is a lack of studies that recruit from this population or even report BMI. Some studies, due to the known association between interoception and BMI, exclude those with high BMI (e.g., Höller et al., 2021). This highlights a gap in the literature related to the modification of interoception for people living with obesity.

Warschburger et al.'s (2022) study protocol states its aims to train interoceptive ability to support a better relationship with food. Known as intuitive eating, this approach supports people to eat in line with the body's needs of satiety and hunger and give the self unconditional permission to trust these cues (Herbert, 2020; Tribole & Resch, 2020). The study intends to use mindfulness-based techniques including body scan to support body awareness. There is a conceptual link between interoception and intuitive eating, with studies demonstrating interoceptive accuracy mediates the negative association between intuitive eating and body weight (Herbert et al., 2013). Although Warschburger et al. (2022) study does not intend to recruit those with high BMI, it is promising in showing research interest in modifying the awareness component of interoceptive sensibility to support adaptive eating behaviours. This exemplifies the importance of interoception as a target for intervention within the context of novel, weight inclusive approaches to support people living with obesity.

Heart Rate Variability

Alongside the study of interoception, physiological measures of ER have been investigated which provide more insight into the biological underpinnings of ER as well as possible approaches to modulate ER. Heart rate variability (HRV) is the variability of time between heart beats. HRV is considered an index of ANS functioning and is linked to ER (Cattaneo et al., 2021; Shaffer et al., 2014). High levels of variability indicates high levels of flexibility and resilience in an individual such that their physiological systems are able to

adapt to the environment supporting optimum functioning (Shaffer et al., 2014). HRV is constantly adapting and fluctuating throughout the day in response to external and internal triggers to achieve homeostasis in the body (Shaffer & Ginsberg, 2017).

The network of nerves that are responsible for functioning of the heart come from the SNS and PNS (Shaffer & Ginsberg, 2017). The SNS serves to shorten the interval between heart beats and the PNS promotes prolonged intervals (Pinna & Edwards, 2020). HRV is therefore a useful, non-invasive tool for measuring ANS activity (Acharya et al., 2006). The vagus nerve, a key component of the PNS is reliably measured through HRV (Shaffer & Ginsberg, 2017). Overall, low HRV indicates sympathetic tone (fight or flight) compared to high HRV which indicates parasympathetic activity (Pinna & Edwards, 2020; Shaffer et al., 2014).

Low HRV is consistently recorded in people living with obesity (Strüven et al., 2021). HRV is significantly associated with better ER in the form of reappraisal strategies compared to emotional suppression (Pinna & Edwards, 2020). This is interesting, given the evidence for the increased use of suppression strategies in people with obesity (Fernandes at al., 2018). Pinna and Edwards (2020) conclude that HRV is a biomarker of adaptive ER. Therefore, it is an interesting variable to consider in the measurement of interventions aimed at modifying ER. Breathing at a slow and steady rate, such as six breaths a minute maximises HRV by stimulating autonomic reflexes (Lehrer et al., 2003; Pham et al., 2021). Slow-paced breathing practices have shown to directly impact ER (Mccraty et al., 2009). These interventions use feedback measures to support individuals to slow breathing, an intervention named heart rate variability biofeedback (HRVB). Lehrer et al. (2014) offer an explanation of the mechanisms, suggesting that HRVB works through restoring autonomic functioning by regulating heartrate. Slow breathing can stimulate vagal tone which supports PNS activation and relaxation (Lehrer et al., 2014; Porges, 2011). This has shown to have clinical implications in

reducing symptoms of depression and anxiety (Lehrer et al., 2014). Overall, the research suggests that HRV, a biomarker of autonomic homeostasis, can be modulated through intentional slow-paced breathing to stimulate vagal tone.

In people with obesity, empirical work has demonstrated heightened vagal tone in response to high calorific foods (Udo et al., 2014). The authors explain that this could represent an increased vulnerability to overeating such foods. This is important, given the role of the vagus nerve in signalling satiety (Owyang & Heldsinger, 2011). This presents the role of vagal activity, as measured by HRV in understanding food related behaviours in people with obesity. Contrary to findings by Udo et al. (2014), Spitoni et al.'s (2017) research group found HRV reductions in response to food which led to poor inhibitory control around food. They advocate for HRVB as a potential therapeutic tool for people with obesity. Further research is required to make sense of these convergent findings as both studies employed relatively small samples and differed in their experimental approach (e.g., participants in Udo et al.'s study were food deprived).

In laboratory induced stress situations, there is an association between lower HRV and higher severity of loss of control eating (Godfrey et al., 2019) The authors conclude that poor ANS flexibility is related to increased severity of over eating and loss of control eating for people with obesity. This further substantiates HRV as a biomarker of ANS functioning and ER for this population. It also suggests that HRV can be used to provide valuable psychophysiological data that can be collected passively as part of the evaluation of ER interventions for people with obesity (Godfrey et al., 2019).

Polyvagal Theory

One theory that adopts a bio-behavioural framework and therefore could be applicable to our understanding of interoception in people living with obesity is PVT (Porges, 1995, 2003, 2007). PVT conceptualises the regulation of the ANS through the vagus nerve. The

vagus nerve, commonly referred to as the vagal brake, stimulates and inhibits the SNS. This facilitates adaptive physical and behavioural responses to environmental demands (Porges, 2007). Activation, inhibition and flexibility of the vagal brake and ANS response is vital to enable survival in the face of danger and thriving in response to safety (Dana, 2018; Porges, 2015). An adaptive ANS supports engagement with the social environment to meet the biological imperative of human connectedness (Cacioppo & Cacioppo, 2014).

PVT proposes that the ANS is comprised of three systems: ventral vagal, SNS and dorsal vagal. The ventral vagal system is associated with feelings of safety, social connectedness, communication, curiosity and creativity (Porges, 2011). The SNS, more commonly known as 'fight or flight', represents a state of mobilisation, triggered by threat it supports a drive to defend or flee. In this state, SNS activation leads to physiological arousal including increased heart rate, sweating and pupil dilation. Thirdly, the dorsal vagal system, the most archaic in evolutionary terms, represents a state of immobilisation (Porges, 1995). In this state, individuals can present as behaviourally shutdown, or on autopilot, experience feelings of helplessness, numbness and dissociation. At its most extreme, this can be a freeze response and can explain defensive behaviours in threatening situations such as loss of bladder control which occurs as a result of autonomic physiological shut down (Porges, 2011).

The three-system model is hierarchical in nature such that an individual initially attempts to engage in complex human interaction with the world using the ventral vagal system. When the environment is perceived as safe the ventral vagus nerve inhibits sympathetic system defence reflexes, the vagal brake is on (Porges, 2007). If threat is detected and functionality of ventral vagal for survival fails, the body will physiologically shift into the sympathetic system. Following failure of this response, the body will shift into dorsal vagal, a detached and/or immobilisation response. Each system has an adaptive

purpose and responsiveness of the ANS reflects flexibility of being able to move between states.

Porges (2007) proposes that it is the ventral vagal system that has led to our success as a species due to its ability to initiate pro-social behaviour. Porges calls this our social engagement system and it can be used as a form of safety seeking. When the ventral vagal system is activated, the individual is in a soothing and socially-engaged state and they display pro-social behaviours that support the building of trusting relationships by down regulating (putting the brake on) sympathetic fight/flight behaviours (Porges, 2015). The ventral vagal state comprises a complex interaction between the heart and facial muscles that produce cues of safety that we project and also look for in others to support social connection and engagement (Porges, 2011). This includes facial expressions of smiling, eyebrow movements, posturing and vocal tone that signal safety. We look for these cues of safety in others and reciprocate these to project cues of safety to others to foster connection. This is known as co-regulation (Porges, 2011).

Adaptive regulation of the ANS and vagus nerve underpins healthy ER (Balzarotti et al., 2017) and has been measured through HRV (Porges, 2007). Failures in this functionality can give rise to psychopathology and emotional dysregulation (Cattaneo et al., 2021). Atypical vagal regulation has been associated with psychiatric disorders such as borderline personality disorder (BPD; Austin et al., 2007; Meyer et al., 2016). Austin et al. (2007) found that in response to emotion eliciting film clips, the BPD group demonstrated less flexibility in their vagal activity (low HRV) and more pronounced emotion dysregulation. This is explained by authors to evidence PVT as it demonstrates the link between vagal activity, ER difficulties and psychopathologies as a result of ANS dysfunction (Austin et al., 2007; Cattaneo et al., 2021).

Homeostasis is achieved through bidirectional communication between the peripheral organs and the brain through a neural process called neuroception (Porges, 2007). Neuroception is the preconscious evaluation of threat in environmental cues that affect the senses and trigger a physiological stress response with the intention of preparing the body to deal with the perceived threat. Neuroception takes into account interoceptive, somatosensory and endocrine information and it occurs rapidly, without conscious awareness (Porges, 1993). If cues trigger a neuroception of safety, we feel soothed, calm and able to interact with others. In this, our ventral vagal state is active. However, if cues triggers a neuroception of danger, our vagal brake is released, and the body mobilises a fight/flight response (Porges, 2015). Cues can be both internal and external in the environment. When there is a mismatch between the actual event and the physiological response initiated, this can give rise to problematic long term physiological and behavioural problems (Porges, 2007). This is because atypical physiological reactions can limit the range of emotional expression and quality of communication (Porges, 2007).

PVT takes into account the interaction between the ANS and the external environment that contributes to our experience of the world. The ANS is constantly learning information from our environment that shapes our experience of future events. For example, adverse childhood experiences (ACEs) can lead to the ANS being hypersensitive to threat and reducing an individual's capacity to respond to their environment adaptively (Flores & Porges, 2017; Rovnaghi & Anand, 2018). PVT offers an attachment-based framework, explaining how a responsive caregiver in early life mediates the attachment bond through the social engagement system (Porges, 2003). Social connection with others is imperative for our survival and we are biologically wired to make connections and be social beings (Cacioppo & Cacioppo, 2014). Activation of the ventral vagal and a neuroception of safety is the important first step in forming an attachment (Porges, 2003). Reciprocal regulation between infant and

caregiver are the first opportunity to co-regulate and serves to tone ventral vagus (Apicella et al., 2013). Therefore, disruption to early life attachments and opportunities for toning the nervous system can serve to increase the perception of threat, ANS dysregulation and neuroception of danger which maintain defensiveness (Porges, 2003, 2011). This is an important consideration for people living with obesity given that ANS functioning underpins interoception (Khalsa et al., 2018) and therefore may further contribute to interoceptive difficulties for this population.

Challenges to PVT lie in the difficulty to empirically test the interactional underlying neural mechanisms and biobehavioural processes. The notion that vagus nerve functioning in mammals is superior and evolutionarily distinct to other vertebrates such as fish and reptiles has been questioned through evidence showing similar PNS imposed control of heart rate in these animals (Grossman & Taylor, 2007; Taylor et al., 2022). Critics state these findings bring the biological underpinnings of PVT into disrepute. Though this does not question the validity of the social connection aspect of the model, Grossman and Taylor (2007) argue that PVT overlooks the complexities between HRV, vagal tone and behaviour. This sentiment is supported by a commentary piece by Mehling (2021) who agrees that PVT oversimplifies the neural underpinnings of human behaviour. However, Medeiros et al. (2021) state that despite these criticisms, it remains a valid model for clinical application and the interpretation of psycho-physiological dynamics. This position, unsurprisingly, is corroborated by Porges (2011) who states that even if biological ANS functioning does deviate from that prescribed by PVT, there is observational evidence for the behaviours that arise from shifts in the ANS and for the social engagement aspects of the model which demonstrates an ecological validity to the ideas. For example, Geisler et al. (2013) found that increases in HRV, representing increased vagal tone and down regulation of the SNS, were associated with better ER and social engagement. In their two studies, they first established a link between HRV, ER and

social engagement using retrospective reporting. Then they built on this by using EMA over a 28-day period. They found that HRV predicted the use of more adaptive ER strategies including social support seeking and less use of maladaptive strategies such as avoidance. They use this to provide empirical evidence for PVT in demonstrating the link between vagal activity, ER and social engagement.

Polyvagal Theory in Therapy

Whilst we cannot necessarily control the triggers of neuroception of danger and the subsequent ANS shifts, we can become aware of the bodily responses (Porges, 2015). Psychological therapy presents an opportunity for neural regulation of the social engagement system. In this, the client can shift from states of threat to calm in the therapy room, based on cues of safety or danger which can support resilience to cope with day-to-day life disruptions (Porges, 2015). Through practicing regulation strategies in the safety of the therapeutic context, ER can be improved (Dana, 2018). PVT is relevant to therapy due to the nature of the work that requires the processing of difficult emotions, memories and experiences which can evoke a threat reaction in the individual (Ryland et al., 2021). Deb Dana (2018) was originally interested in the theoretical application of PVT to therapy for people who have experienced trauma given the physiological manifestation of trauma (van der Kolk, 2014, 2018). However, the clinical applications of PVT have since been expanded for many populations and clinical presentations (Porges & Dana, 2018). PVT informed therapy (PVTT) socialises individuals to the PVT perspective of the ANS and therefore provides validation and normalisation of people's natural bodily processes and the interaction between their body and the environment in response to threat (Dana, 2018).

In therapy, the three-system hierarchy can be presented diagrammatically on a ladder to support lay socialisation to the PVT model (Dana, 2018). Through this deepened understanding of their ANS, clients can recognise the autonomic state, foster non-

judgemental respect for the physiological shifts and the survival response and regulate through the teaching of behavioural techniques. Regulation techniques include slow paced breathing which elongates the out breath to stimulate the PNS and activate the vagal brake (Porges, 2017). These 'top down' self-regulatory techniques are further solidified by the presence of the therapeutic relationship which serves as co-regulation (Geller & Porges, 2014). The formation of a trusting relationship between therapist and client is facilitated through the therapist conveying cues of safety including empathic listening behaviours, warmth in tone of voice and gentle eye contact (Geller & Porges, 2014). This triggers a neuroception of safety, supporting co-regulation and allowing the client to foster their ventral vagal state to support psychological wellbeing (Dana, 2018). Understanding how the therapeutic alliance can contribute to improved regulation and wellbeing is of particular relevance, given the importance of the therapeutic alliance in the effectiveness of psychological interventions (Geller & Porges, 2014; Norcross & Lambert, 2011). PVT has also been applied to explain resistance in therapy (Ryland et al., 2021). Client displays of avoidance, homework non-compliance, disagreement or even lack of attendance can be seen as protective responses and conceptualisation of resistance through this lens can foster understanding, compassion and reduce resentment from therapists (Ryland et al., 2021).

Empirical Support for PVTT

The clinical application of PVT within the literature tends to focus on conceptualising a phenomenon through a PVT lens. For example, using PVT to understand co-parenting litigation cases (Bailey et al., 2020), conduct problems in children (Beauchaine et al., 2007) and even to understanding patient responses to Covid-19 (Hanscom et al., 2020). This application of PVT is deductive and retrospective in nature, as opposed to using PVT to inform the intervention and therefore directly test PVTT. More specific to psychological interventions, Lucas et al. (2018) incorporated a PVT framework to understanding

mindfulness-based movement for cancer survivors. Authors explained that creating a sense of safety that promotes pro-social connection and engagement, supports the effectiveness of mind-body interventions. This is of relevance to an obese population, given the difficulties in trust in their bodies and the necessity of creating a safe space to explore bodily sensations (Calì et al., 2015; Willem et al., 2021). However, Lucas et al. (2018) also draws on PVT retrospectively to understand mindfulness-based movement, rather than empirically testing PVTT. This retrospective approach has been adopted in other papers of contemplative practice (Sullivan et al., 2018). However, to the authors knowledge, PVT has not yet been directly applied to working with people with obesity.

Despite the promise of PVTT as a theoretical model, it is simply put, just a model at this stage. The papers outlined above are theoretical and narrative in nature, and do not empirically test PVTT in practice. There appears to be a paucity of empirical research examining the effectiveness of this therapy in applied settings. Two published books (Dana, 2018; Porges & Dana, 2018) provide comprehensive guides to utilising PVT clinically though these mostly rely on anecdotal accounts without peer-reviewed empirical work that tests the use of PVT in clinical settings with scientific rigour. This leaves a chasm of evidence that has yet to be filled and could reflect the relative novelty of the use of PVT in clinical practice. However, given that PVT is being anecdotally used in clinical settings, it is imperative it is subjected to scientific examination so that it can be justifiably included or disregarded as an evidence based clinical intervention.

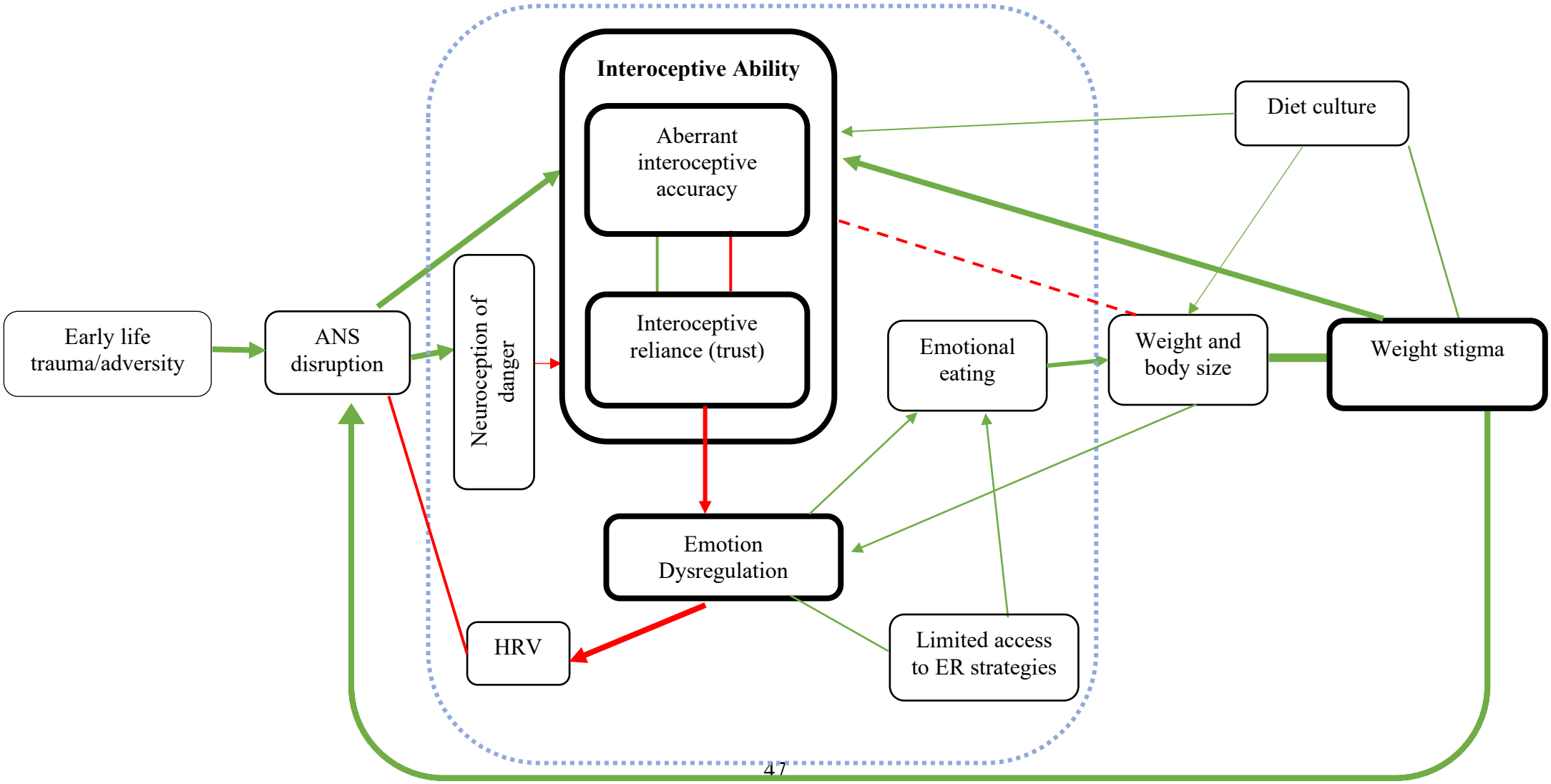
The Theoretical Application of Polyvagal Theory for People Living with Obesity: A Proposed Model

Taken together, there is a complex feedback system between early life experience, autonomic functioning, interoception, ER, obesity and societal influences that serve to impact meaning making of bodily signals and influence behaviour. Theoretically PVTT has the

potential to integrate overlapping areas in the literature to provide a holistic and effective treatment for people with obesity and emotion dysregulation. Figure 1 depicts a proposed model that integrates the literature presented in this review drawing on network analysis (Borsboom, 2008; McNally, 2016). In network analysis, the model is more dynamic as it reflects how the variables interact and their relative importance with one another. This type of model is relevant to interoception in obesity as it allows for an understanding of the dynamic and complex interactional processes involved, all of which may present to differing degrees for an individual but together, in their summation present as a clinical problem. In line with the guidance set out by McNally (2016), Figure 1 presents key factors, known as nodes, in rounded edge squares connected to other nodes by edges (lines). Red edges represent negative associations such as that between low interoceptive reliance and high emotion dysregulation (Willem et al., 2021). This is compared to green edges which represent positive associations such as the relationship between high EE and increased weight and body size (Fuente González et al., 2022). Edges without arrows reflect bidirectional relationships between nodes such as that between body size and weight stigma (Puhl et al., 2020). The weighting of edges and nodes represents its level of importance and the degree of associations such that heavier weighted lines indicate increased importance, association and/or evidence. For example, the relationship between weight stigma, body size and ANS functioning is well established across experimental and prospective studies (Jackson et al., 2015; Puhl et al., 2020; Vadiveloo & Mattei, 2017). The edge between weight gain and interoceptive ability is dashed as although a relationship has been established between these, the direction of the relationship is still disputed (Robinson et al., 2021).

Figure 1

A Proposed Model of Interoception in People Living with Obesity



Note. ANS = autonomic nervous system; HRV = heart rate variability; green edges represent positive associations; red edges represent negative associations; arrows indicate direction of relationship; an absence of arrows indicates a bi-directional relationship; dashed lines indicate unknown directionality and dotted line indicates area of focus for therapeutic interventions.

In consideration of this proposed model, a number of maintenance loops are presented which offer opportunities for intervention. It is important to recognise the variables that individuals can exert more and less control over. Systemic issues that affect people with obesity require cultural and public health changes that can take many years and, in that time, will continue to act on and effect individuals. This is evident from the lack of societal changes in relation to weight bias (Charlesworth & Banaji, 2019; Pearl & Schulte, 2021). The corner stone of psychological approaches, is the idea that people can have an element of control about how they respond to the emotional and behavioural aspects of external factors (Van Dorsten & Lindley, 2008). With this in mind, it is the central maintenance loop highlighted by the blue dotted box that provides a plausible area for therapeutic target, namely targeting ER as the outcome for change (Fernandes et al., 2018) through the process of improving interoception (Craig, 2015; Wiens, 2005), whilst cultivating trust (Willem et al., 2019, 2021) and providing increased access to adaptive strategies to support ER (Fernandes et al., 2018; Gianini et al., 2013).

Whilst there are pockets of research into interoception and ER, and cross-sectional data on the role of ANS functioning (HRV) in people with obesity, there is a lack of integration across these fields which overlooks the multifactorial nature of difficulties associated with obesity. PVT offers an integrated mind-body understanding that combines interoception, vagal tone and ER and has direct clinical implications for this population. PVT offers a comprehensive understanding of the ANS and its applicability to phenomenological experience and threats (Porges, 2007). In particular, it's contribution to therapy has scope to

overcome difficulties related to trusting bodily signals for people in bigger bodies, which is vital for interoceptive sensibility and thus adaptive functioning (Füstös et al., 2013; Willem et al., 2021). Understanding bodily reactions to cues of threat and safety and the role of neuroception also allows consideration of the impact of societal factors on people living with obesity. This is an area overlooked by current interventions (Puhl et al., 2020). PVTT has the potential to aid understanding and recognition of weight stigma, trauma and diet culture as threats that serve to maintain dis-trust with the body and emotional distress.

PVTT may also bridge the gap in difficulties associated with ER in people with obesity. Currently, research suggests that individuals must be able to identify the emotion as a precursor to appropriately regulating and coping with the emotion (Gianini et al., 2013). Socialising clients to the workings of the ANS can serve to normalise and validate physiological changes that underpin emotional experience (Dana et al., 2018). This is vital for this population who struggle to identify emotions and experience considerable body related shame (Puhl et al., 2020).

Future Directions

Whilst there is theoretical credibility, empirical research is needed to determine the validity and usefulness of PVTT with obese individuals. The following research questions require addressing: is PVTT an effective treatment for improving interoception and emotion regulation in people with obesity? Is PVTT acceptable for use with this population?

There is great heterogeneity in the population of people living with obesity as disordered eating is often co-morbid with psychiatric disorders such as ADHD (Kaisari et al., 2017) and depression (Simmons & DeVille, 2017). Additionally poor interoception is a facet of anxiety and depression (Pollatos et al., 2009). Therefore, strict inclusion and exclusion criteria that is commonplace in research would exclude many people and therefore not be representative or thus generalisable to the population. Furthermore, group comparison

analyses would not account for possible confounding variables. Therefore, a single case experimental design (SCED) is better suited to answer these research questions. Firstly, a SCED allows for heterogeneity in the sample as individuals act as their own controls (Morley, 2017). A baseline period allows for understanding into the existing nature of the target variables and therefore a period of comparison which aids to support understanding of treatment effects for an individual (Kazdin, 2019). As participants act as their own controls, a more tailored and flexible approach to the intervention can be taken to meet the individual's needs. This is relevant for our understanding of interoception, which can falter at various stages for different people (Murphy et al., 2017), alter in various facets (Nord & Garfinkel, 2022) and present differently due to its associations with psychopathologies (Pollatos et al., 2009).

Another benefit of SCED is the use of idiographic measures that ask about target problems that are meaningful and relevant to the individual, capturing the content of a difficulty rather than a construct (Morley, 2017). Although open to criticism due to their lack of validation, idiographic measures hold criterion validity due to their direct nature (Kazdin, 2019; Morley, 2017). These can be collaboratively created with participants and allowing choice and tailoring of idiographic questions has shown to improve motivation and engagement with measures (Miles et al., 2019). This should be considered in the design of measures to support engagement when completing measures multiple times, and in the absence of monetary incentives which can bias samples. This could be a valuable way to overcome difficulties in finding low internal consistency with standardised measures which has led to certain subscales of the MAIA having to be excluded from analyses in paper (e.g., Todd et al., 2019).

Given the evidence for considerable intra-person variability across all three facets of interoception (Höller et al., 2021; Wittkamp et al., 2018), the measurement of interoception is

well suited to frequent, daily measures that provide high temporal resolution. This can be achieved through ecological momentary assessment (EMA) and also lends itself to the repetitive use of daily measures in single case design. Höller et al. (2021) used EMA and established no practice effects for items on the MAIA except the attention regulation subscale. This demonstrates the feasibility of measuring interoception repeatedly over time. This may also serve to overcome drawbacks of cross-sectional studies of interoception in obesity that take static measurements (Robinson et al., 2021).

Despite there being no evidence of practice effects, there is a possibility of maturation effects. This is changes to measured outcomes that can occur over time irrespective of treatment and adoption of a multiple baseline design between subjects can serve to protect against this threat to internal validity (Vannest & Ninci, 2015). As subjects complete differing lengths of baseline period, any changes to outcomes can be attributed to the only manipulated factor, treatment (Morley, 2017). Further controls can be applied by randomising participants to baseline lengths and having at least three baseline lengths in order to demonstrate a replication of effect and experimental control (Horner et al., 2005; Kratchowill, 2010; Kazdin, 2019). This comprehensive design will allow for confidence and validity in causal effects to either be established or falsified. To understand the durability of any treatment gains, research should continue to measure variables once the treatment has come to an end. This can be conducted within SCED with the inclusion of a follow up phase. The application of this design would allow for thorough scientific investigation of the effectiveness and durability of PVTT for people living with obesity.

To complement the idiographic measures, standardised measures should also be used in answering the proposed research questions. Critique of the MAIA as a measure of interoception has been related to its open time frame in the instructions which can be subject to memory bias (Ebner-Priemer & Trull, 2009). SCED allows for repeated collection of

measures over multiple time points. This, therefore, lends itself well for adaptation to the measure instructions specifying participants to reflect on the past week. Although it is not specified whether they altered instructions, Bornemann et al. (2015) have demonstrated that MAIA is sensitive to change. Other variables of interest, namely, ER measured by standardised measures would also require similar adaptations to specify a time period. The commonly used difficulties in emotion regulation scale (DERS; Gratz & Roemer, 2004) has been used in obese samples (Willem et al., 2019) but does not specify time in the standardised instructions. However, it has been used in multiple time point studies demonstrating sensitivity to change (Gratz & Tull, 2011). This provides a basis for modifying the instructions in both of these standardised measures for the use in SCED. The use of standardised measures will allow for comparison to pre-existing literature, norms and provide communicable contributions to the field. Furthermore, having multiple standardised measurements pre-treatment means fluctuations in baseline can be checked and contribute towards controlling for regression to the mean (Morley, 2017).

Measures can be further complemented through the use of an objective measure of ER and vagal tone. HRV has been posited as an important variable that can easily be collected as part of intervention evaluations to detect any physiological changes as a result of the intervention (Godfrey et al., 2019). Measurement within SCED allows for recordings of baseline HRV to be collected as a comparison which can reduce risk of systematically low HRV in this population biasing interpretations (Strüven et al., 2021). Photoplethysmography (PPG), which uses a light source through smartphones can be used to measure HRV and is comparable to electrocardiogram measurements (ECG; Giardino et al., 2002; Schäfer & Vagedes, 2013). The use of PPG allows for non-invasive remote collection of data via smartphone apps which would be suitable for this kind of design. Repeated measures collected each day allows for insight in the variability of HRV, which can be affected by

sleep, caffeine, stressors and age (Shaffer et al., 2014; Strüven et al., 2021; Umetani et al., 1998). Given that the heart is not a metronome, participants should be encouraged to take HRV first thing in the morning to avoid, as much as possible, the influence of stressors and provide comparable data day to day (Shaffer et al., 2014). Measuring HRV can serve to examine the effectiveness of PVTT in its ability to modify physiological processes like that seen in HRVB (Elliot et al., 2004; Lehrer et al., 2003; Mccraty et al., 2009).

Overall, the use of SCED to answer the main research question provides a rigorous scientific research methodology that allows for the comprehensive evaluation of novel interventions (Kazdin, 2019, Morley, 2017). To ensure high standards in the conducted research, published standards for SCED including What Works Clearing House (WWC; Kratochwill, 2010; WWC, 2017, 2022) and the Single-Case Reporting Guideline In Behavioural INterventions (SCRIBE; Tate et al., 2016) should be followed.

The devised PVTT protocol for research should pay attention to three particular areas highlighted by the literature review to ensure it is applicable to this population. Given the nature of poor interoception in this group (Robinson et al., 2021), time should be given to socialisation to the PVT conceptualisation of the ANS in order to provide a foundational understanding of physiology from which clients can map on their own behavioural and ANS shifts. Importance is placed on socialisation to the model by Dana (2018) and she advocates for this to be facilitated through multimedia such as the use of videos, exercises and images. Given the educational nature of this initial part of the intervention, it is plausible that there will be a latency in treatment effects that should be taken into consideration for data analysis plans. This links to the time needed in therapy to support clients to learn to attend to their bodies, recognise the autonomic state in the moment and respect physiological shifts (Dana, 2018).

Secondly, given the impact of weight stigma and diet culture on people with obesity (Puhl et al., 2020; Tribole & Resch, 2020), fostering a safe and supportive environment is essential. Acknowledgement of the impact of these on the individual is in line with national policy on understanding the multifactorial processes related to obesity (DHSC, 2007). This can be achieved through the therapist offering cues of safety and connection in their warm and authentic nature, signalling unconditional positive regard for the client (Dana, 2018). Drawing on PVT to support people to understand their threat response can serve to normalise and validate their experience with the intention of fostering trust with the body, an essential construct for those with bigger bodies (Willem et al., 2021). It is from a place of trust, that people can tune into their bodily signals and therefore have more choice about to respond to them (Calì et al., 2015; Dana, 2018; Willem et al., 2021).

Thirdly, the intervention should provide individuals with a number of behavioural strategies to promote ER. This is due to the evidence of people with obesity having difficulties not only identifying emotions and bodily sensations, but also having access to ER strategies (Fernandes et al., 2018; Gianini et al., 2013). Measuring interoception and ER as the main outcomes and considering these three areas of focus for the intervention places emphasis on health-related outcomes that are weight inclusive thereby making a healthy and progressive contribution to the field (Hunger et al., 2020).

Alongside effectiveness, it is important to examine the acceptability of PVTT for this population. Acceptability can support successful implementation of interventions and the likelihood of treatment adherence and improved outcomes for people living with obesity (Diepeveen et al., 2013; Stok et al., 2016). The Medical Research Council and National Institute for Health Research stipulate the importance of measuring acceptability of healthcare interventions (Craig et al., 2008; Moore et al., 2015). The theoretical framework of acceptability (TFA; Sekhon et al., 2018) has been used to overcome debates in the literature

around the definition of acceptability in relation to healthcare interventions, by providing a theory driven and empirically tested framework. From this, Sekhon et al. (2022) devised and validated a generic acceptability questionnaire that can be tailored to the specific intervention. This covers the multifaceted nature of acceptability including: affective attitude (how they feel about the intervention), burden (the amount of effort required), ethicality (the goodness of fit with values), opportunity costs (whether benefits are worthwhile given drawbacks), perceived effectiveness (how likely they perceive it is to make a difference), intervention coherence (how well they understand the intervention and how it works), and self-efficacy (their perception that they can make suggested changes). Responses to acceptability questionnaires can be subject to social desirability bias, therefore anonymity in this measure should be ensured to negate this possible threat.

Conclusion

In conclusion, this review proposes a theory and evidence based conceptual framework to understanding and targeting interoception in people living with obesity from a polyvagal perspective. Whilst there is evidence of the link between interoception and obesity, the next step is to establish effective interventions to improve interoceptive abilities in this group to support ER and psychological wellbeing. PVTT may offer an approach that can meet this need. Synthesis of the literature highlights important research questions that require empirical testing. Namely, testing the effectiveness of PVTT as a weight inclusive approach to improve interoception and ER for obese populations through rigorous scientific methodology.

Chapter III: Polyvagal Informed Therapy for Body Awareness and Managing Emotions for People Living with Obesity: A Multiple Baseline Study

Abstract

Difficulties in emotion regulation for people living with obesity has been posited as an important therapeutic target. Interoception, the ability to sense bodily signals, is thought to underpin emotional experience and is impaired in people living with obesity. Specifically, the ability to trust bodily senses, a distinguishing facet in obesity, is overlooked by current emotion regulation therapies for people living with obesity. Polyvagal theory in therapy (PVTT) offers a novel treatment to support body awareness and provides behavioural strategies to regulate the vagus nerve of the autonomic nervous system (ANS). Whilst this has theoretical applicability, it has yet to be empirically tested and evaluated in relation to this population.

This study aimed to investigate the acceptability and effectiveness of PVTT to improve interoception and emotion regulation for people living with obesity. It was hypothesised that the intervention would be associated with improvements in idiographic, standardised and process measures of interoception and emotion regulation. Daily recordings of heart rate variability (HRV), as a measure of vagal tone, were hypothesised to increase, reflecting improved ANS regulation as a result of the intervention.

This study adopted a multiple baseline single case experimental design, recruiting nine participants from an NHS specialist weight management service. Participants were randomised to a one-to-three-week baseline period prior to receiving up to six intervention sessions. Post-intervention, participants completed a three week follow up period. Visual and statistical analyses showed that relative to baseline, there was evidence of improvement of interoception for four participants. Standardised measures were subjected to reliable change (RC) and clinically significant change (CSC) analysis. This demonstrated RC for six participants on standardised measures of interoception. Five participants improved on idiographic measures of emotion regulation and two showed CSC on standardised measures.

Five participants demonstrated significant frequency reductions in their chosen emotion regulation behaviour, three of which chose a form of emotional eating. The majority of participants who completed follow up, continued to improve or sustained treatment gains at follow up. There were minimal changes in relation to HRV. Two participants showing reductions in HRV, contrary to hypotheses. PVTT was rated as highly acceptable by participants.

This study provides promising findings that PVTT is acceptable and effective for improving interoception and emotion regulation for people living with obesity and warrants further research. Limitations and strengths of the study are discussed alongside future directions.

Introduction

Health Survey for England (2021) reported that almost two thirds of the UK adult population are either overweight or obese. These classifications are defined by body mass index (BMI), a calculation of a person's metric weight divided by the square of their height, which categorises those with a BMI of over 25 as overweight, and above 30 as obese (World Health Organisation [WHO], 2021). Rates of obesity are rising, with figures in the UK predicted to rise by 11 million by 2030 (Health Survey for England, 2021; Wang et al., 2011). This is concerning due to the associated risks between obesity and cardiovascular disease, the leading cause of death worldwide, and other life limiting conditions such as diabetes and cancers (WHO, 2023). These comorbidities are accompanied by a high economic burden on UK health systems (Haase et al., 2021; Wang et al., 2011). Health risks are not isolated to the physical consequences of excess weight. Societal perceptions of people in bigger bodies locates the problem within the individual, evoking stereotypes of laziness and poor self-discipline (Pearl & Puhl, 2018; Puhl et al., 2020). Weight stigma has a profound impact on emotional suffering (Brewis, 2014), body image and mood (Stevens et al., 2017) and has been proposed by several authors to drive population levels of obesity (Brewis, 2014; Pearl et al., 2019; Puhl et al., 2020). In light of this, effective interventions and policies to support people with obesity and associated difficulties have garnered international research attention (Swinburn et al., 2019).

People living with obesity have particular difficulties with ER compared to those in the normal weight range (Fernandes et al., 2018). Meta-analyses evidence particular difficulties with identifying feelings, lower levels of emotional awareness and difficulties employing ER strategies (Fernandes et al., 2018). Fernandes et al. (2018) concluded there is no evidence for a general emotion-processing deficit in obesity but that the presence of an emotionally avoidant style may inhibit adaptive ER. An emotionally avoidant style can lead

to seeking external means of regulation in the form of excessive eating as a strategy to cope with negative emotions (Gianini et al., 2013). Emotion suppression is a distinguishing characteristic between severely obese and moderately obese individuals (Andrei et al., 2018). This avoidant and suppressive style is often coupled with increased impulsive behaviours in obese compared to normal weight individuals which links to overeating tendencies which maintain difficulties (Willem et al., 2019). Therefore, one area that has been targeted in psychological therapeutic approaches for people living with obesity is emotion regulation (ER).

Another area that has been targeted in psychological approaches is eating behaviours. Excessive eating in response to emotions without feelings of hunger is known as emotional eating (EE) and is well evidenced within this population to maintain psychological and weight difficulties (Konttinen et al., 2019; van Strien, 2018; Zijlstra et al., 2012). The severity of EE has been found to positively relate to BMI in a recent review and meta-analysis (Vasileiou & Abbott, 2023). This is because EE is associated with a propensity to eat energy dense, high fat, high sugar foods which are highly palatable (Fuente González et al., 2022). EE provides short term comfort which can psychologically reinforce the behaviour (Macht, 2008) and it has been linked to the activation of neural reward systems as a vulnerability and maintenance factor (Dalton et al., 2013). However, heterogeneity of findings in this field have led researchers to advocate for more idiographic approaches (Dalton et al., 2013).

Interventions that target ER for people living with obesity target EE as the main outcome. The most common approaches include mindfulness, acceptance and commitment therapy (ACT), cognitive behavioural therapy (CBT) and dialectical behaviour therapy (DBT; Frayn & Knäuper, 2018). The active components of these interventions have been marked as the ability to accept emotions, regulate internal disinhibition and regulate emotions through alternative skills (Frayn & Knäuper, 2018). A recent systematic review by Smith et

al., (2023) synthesised 34 intervention studies that addressed EE in adults with overweight and obesity. They found that CBT followed by ACT showed the highest percentage of change in EE behaviours. The authors attribute this change to the focus on identifying emotions and the introduction of alternative coping responses. Given that mindfulness skills are a key component of ACT based interventions (Warren et al., 2017), Smith et al. (2023) concluded that the combination of CBT with mindfulness is superior. This is because it supports individuals to accept emotional states to reduce EE, whilst learning behaviour change techniques. It is clear from the Smith et al. (2023) review that interventions to support ER in people with obesity should draw on the role of acceptance of emotional states and behavioural interventions coping strategies.

Several limitations of these reviews must be noted. In particular, there are methodological limitations due to the variety of measurement tools of EE. The most commonly employed tool is the Dutch Eating Behaviour Questionnaire (DEBQ). The validity of the DEBQ has been criticised as it overlooks individual differences such as the impact of mood on reliability of reporting and lacks correspondence to actual EE behaviours (Domoff et al., 2014). Also, many of the included studies focus on weight loss as the primary outcome (Chew et al., 2022; Frayn & Knäuper, 2018; Smith et al., 2023). This outcome theoretically may come secondary to reductions in EE and is therefore not captured within the study time frame (Smith et al., 2023). This calls for more tailored interventions that speak directly to the underlying mechanisms of ER (Frayn & Knäuper, 2018).

The underlying mechanisms of emotional experience can be understood as bottom-up input signals, bodily sensations that involve visceral-afferent signals coordinated by the central nervous system (Craig, 2015; Wiens, 2005). This is called interoception. A recent review and meta-analysis established an association between deficits in interoception and higher BMI (Robinson et al., 2021). Willem et al. (2021) specifically highlight the

contribution of interoceptive reliance; a component of interoceptive sensibility that is the ability to trust the body's signals. Willem et al. (2019) found that when examining interoceptive facets, obese individuals had significantly pronounced difficulties with observing, noticing and trusting bodily sensations as measured by the multi-dimensional assessment of interoceptive awareness (MAIA, Mehling et al., 2012) compared to normal weight individuals. They found less mindfulness abilities in this group related to being able to observe and describe sensations which they noted reflects subjective interoceptive awareness. This supports prior research on the role of aberrant interoceptive abilities in obesity (Fassino et al., 2004; Herbert & Pollatos, 2014). Willem et al., (2019, 2021) propose that for adaptive functioning, an individual must be able to accurately detect bodily signals (e.g., heart racing) and then be able to trust that this is a reliable sensation (e.g., anxiety) in order to respond appropriately (e.g., take deep breaths). This highlights the interactional processes between physiological, neural and cognitive processes. Fostering trust in bodily signals alongside noticing these signals is necessary to overcome possible risks of emotional distress and poor ER strategy employment (Calì et al., 2015). Therefore, trust in bodily signals should be considered as an essential component in psychological treatments that target interoception for this population (Willem et al., 2019).

Alongside research into the role of interoception in emotional experience, heart rate variability (HRV) has been coined as a biomarker of self-regulation (Beauchaine & Thayer, 2015). HRV is the variation in heartbeat intervals (Shaffer et al., 2014) and represents vagal tone, the underlying physiological processes of the ANS and its ability to adapt in response to perceived threats and risks (Shaffer & Ginsberg, 2017). Poor ER has been linked to low HRV generally (Holzman & Bridgett, 2017) and specifically in those with heavier body weights where it is also linked with loss of control eating (Godfrey et al., 2019; Spitoni et al., 2017, Udo et al., 2014). Top-down modulation of HRV through psychological interventions, such

as mindfulness, has been shown to increase HRV over time, reflecting a more adaptive stress response (Shearer et al., 2016). This presents an interesting objective measure of ER to evaluate psychological interventions.

HRV as a biomarker of self-regulation reflects ANS homeostasis (Pinna & Edwards, 2020; Shaffer et al., 2014). The ANS has been conceptualised from an evolutionary neurophysiological perspective as our social engagement system (Porges, 2003, 2007). Polyvagal theory (PVT) proposes our ANS is comprised of three hierarchical systems: ventral vagal, sympathetic (fight/flight) and dorsal vagal. Ventral vagal is our social engagement system which allows us to be creative and co-regulate. It is driven and regulated by a sense of safety. The commonly named fight/flight system reflects SNS activation, increased arousal and mobilisation in response to threat. The ecologically most archaic system is dorsal vagal which can present as feeling on autopilot, immobilisation and at the extreme, dissociation. Shifts between these physiological states occur as a result of neuroception (Porges, 2007). Neuroception is a rapid process that occurs without awareness, through a preconscious evaluation of possible risks, threats and cues of safety in our environment (Porges, 2003, 2007). Understanding these underlying neurophysiological processes provides the basis of how we navigate our world and emotionally regulate accordingly.

The process of neuroception begins from birth as the child navigates their social world and seeks co-regulation and safety from the main caregiver (Porges, 2015). Adverse childhood experiences (ACEs), such as disruptions to attachment and perceived safety can trigger a sensitivity to threat that is maintained into adult life (Flores & Porges, 2017). ACEs have been evidenced to increase the chances of later life poor mental health (Dube et al., 2003; Felitti et al., 1998). The effects of early life adversity on interoception, ANS and ER must be considered for this population as evidence suggests that EE behaviours in people with obesity are learnt from experiences of mis-attunement and lack of opportunity for

emotional development in the infant-caregiver relationship (Snoek et al., 2007; van Strien, 2018). Furthermore, poor early attachments and unsafe environments can lead to the development of poor interoception (Basile et al., 2019), difficulties in identifying emotions in others (alexithymia; van Strien, 2018) and dysfunctional ER (Rommel et al., 2012; Vandewalle et al., 2014, 2016). This could be explained through a PVT lens as a biological sensitivity to environmental cues, i.e., overactivation of the ANS threat response, which can impact the development of psychological and emotional regulation (Porges 2003, 2009).

This understanding of the ANS and its role in emotional experience and regulation has informed the development of PVT informed therapy (PVTT) which supports people to understand the rhythm of their ANS (Dana, 2018). PVTT supports clients in the safety of the co-regulating therapeutic relationship, to tune into their bodies, recognise autonomic shifts and implement behavioural strategies to self-regulate (Geller & Porges, 2014). The applicability of PVTT to support acceptance and understanding of bodily processes to this population holds promise due to the effectiveness of combining acceptance and practical behaviour change strategies (Smith et al., 2023). It also may serve to overcome previous shortcomings of approaches that fail to recognise the underlying mechanisms of ER in this population (Frayn & Knäuper, 2018). The emphasis on fostering a neuroception of safety could hold promise in directly addressing the difficulties of bodily trust present in this population (Willem et al., 2021), providing further justification for the applicability of this approach to an obese population.

PVTT offers a weight inclusive approach to supporting individuals with interoception and ER, and to the author's knowledge, has not yet been applied to individuals with obesity. Whilst weight loss might be assumed to be the target outcome for interventions, this approach can serve to perpetuate weight stigma as it is underlined by the belief that fatness is causally related to poor health (Puhl et al., 2020; Hunger et al., 2020). Social justice movements such

as Health at Every Size (HAES), promote the idea of weight inclusivity based on the notion that health outcomes can be improved in the absence of weight loss (Bacon & Bacon, 2010). This approach speaks to the complexity of health and serves to directly tackle the impact of weight stigma (O'Hara & Gregg, 2006). Several interventions adopting the HAES approach have demonstrated measurable positive health outcomes including improved blood pressure, self-esteem, eating behaviours and body image (Bacon & Aphramor, 2011; Ulian et al., 2018). Furthermore, such approaches overcome issues with more traditional treatment approaches weight loss is not maintained over the long term, long term health outcomes of morbidity are not improved (Bacon & Aphramor, 2011) and psychological factors are overlooked (Brownell & Wadden, 2016). PVTT offers a promising psychological intervention to address ER in this population that overcomes these shortcomings.

In light of the above, the evidence on the relationship between ANS functioning, interoception, and ER for people with obesity provides potential therapeutic targets (Willem et al., 2021; van Strien, 2018). These include improving interoception, both in terms of noticing signals and improving the sense of trust in such signals to support more functional ER strategies. Previous interventions tend to focus solely on ER and overlook the complex interaction between the body and mind, namely the bottom-up process of interoception. This is particularly important for this population, who are characterised by a seen societal difference in their bodies which affects health outcomes (Puhl et al., 2020). PVTT offers a novel approach to bridge this gap as it combines the understanding, and therefore normalising and validating of the ANS, as a means to support body trusting alongside behavioural techniques to support more functional ER strategy employment.

The Present Study

The present study aims to evaluate the effectiveness and acceptability of PVTT for individuals with obesity using a specialist weight management service in the UK. Single case experimental design (SCED) studies offer a bridge between the laboratory and clinical practice in providing richer data for patients across baseline and intervention phases to further the empirical basis of the discipline (Borckardt et al., 2008). This design is also suitable for the heterogeneity present in the population of people using specialist weight management services. Whilst they have a high BMI and possible weight-related co-morbidities in common, there is heterogeneity in co-morbid mental health diagnoses and eating behaviours (Bolckmans et al., 2023).

PVTT was adapted from Dana (2018) into a six-session intervention that promotes body attunement within the safety of a therapeutic relationship (Geller & Porges, 2014). As interoceptive awareness alone is not sufficient (Willem et al., 2021), a neuroception of safety must be cultivated to support trust in the body to allow for the introduction of behavioural skills to respond adaptively to these cues. Whilst many intervention studies have focused on EE as an outcome, we did not want to exclude individuals for whom another dysfunctional ER strategy occurs with higher frequency and impact on their life. Therefore, one of the idiographic outcome measure questions was open to allow participants to select a personally meaningful ER behaviour. The SCED also allows tailoring of the intervention, which is necessary for this heterogenous group. Therefore, the current study aims to determine whether PVTT is effective for improving interoception and emotion regulation for people using a specialist weight management service. It aims to establish treatment durability by measuring over a three week follow up period and to assess the acceptability of PVTT for this population.

Hypotheses

1. Polyvagal theory informed therapy (PVTT) will lead to post-intervention improvements in idiographic, process and standardised measures of interoception and emotion regulation.
2. PVTT will lead to increased vagal tone as measured by heart rate variability.
3. Changes will be maintained over a three week follow up.
4. PVTT will be acceptable for use within this population.

Method

Participants

In total 11 female participants consented to take part. One participant withdrew following issues with the HRV4Training app. Another participant received a diagnosis of Dementia during the intervention phase and therefore was no longer eligible to take part in the study. This left a final sample of nine participants. One withdrew following intervention session five and all others completed all three phases of the study. Participants were recruited from an NHS Specialist Weight Management and Bariatric Service. Recruitment took place between August and November 2022. The flow of participants and attrition, in line with What Works Clearing House (WWC) standards (2017), is presented in Figure 1.

Inclusion and Exclusion Criteria

The following inclusion criteria were used for the study:

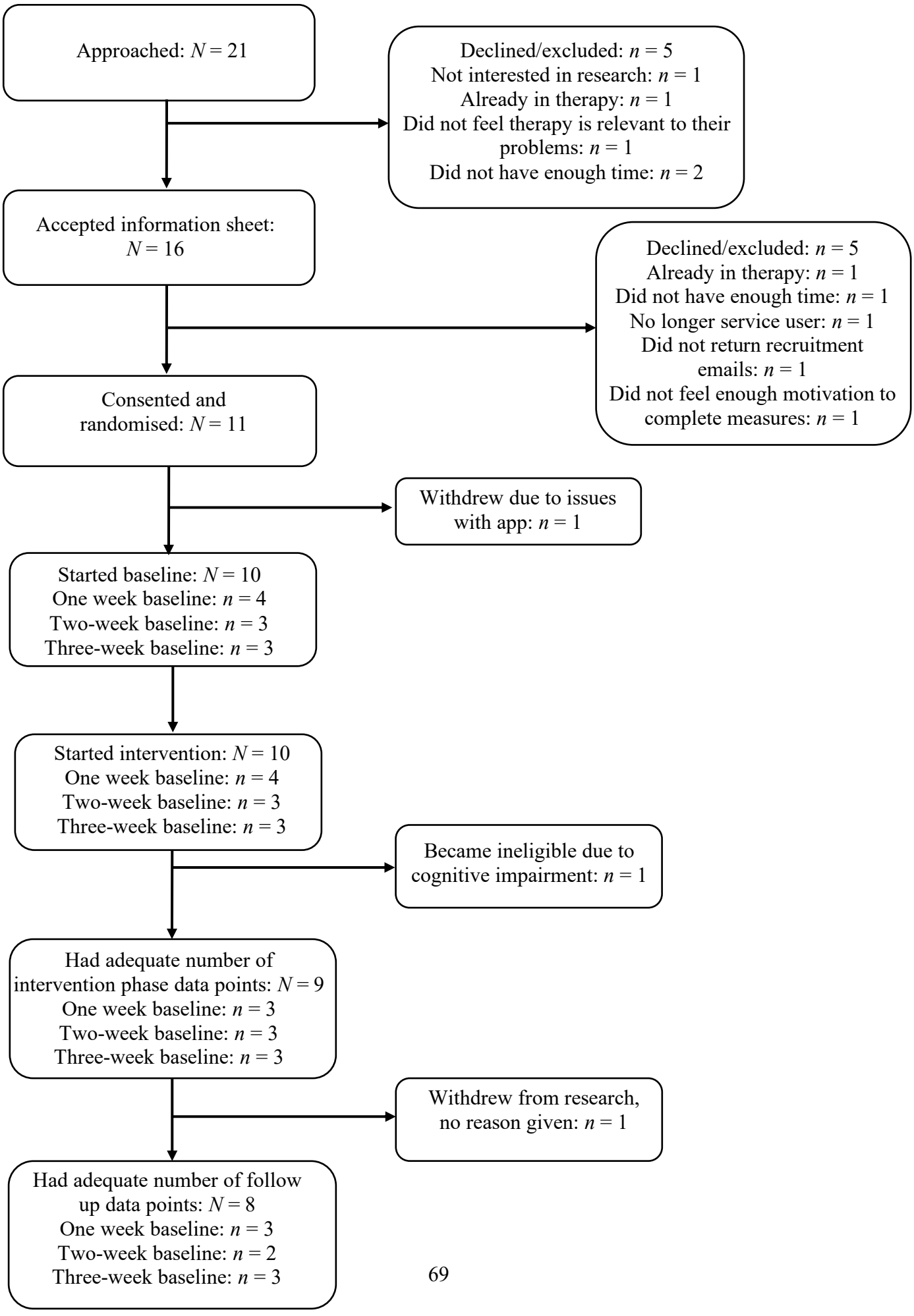
- Service user of NHS Specialist Weight Management Services (this encompasses referral criteria of BMI>30)
- Ages 18-65
- Good level of English reading and writing
- Access to device with internet connection to complete online questionnaires
- Ability to access remote sessions using Attend Anywhere with camera
- Ability to commit to full study period of up to 16 weeks

The following exclusion criteria were used for the study:

- Currently in psychological therapy treatment during the 16-week study period
- History of organic brain injury or cognitive impairment
- Clients presenting with suicidal intent

Figure 2

Flow of Recruitment and Participation



Recruitment

All participants were recruited from an NHS Specialist Weight Management and Bariatric Service. All clinical staff members were briefed on the nature of the study and inclusion and exclusion criteria. Potential participants were identified by their direct clinical team during routine clinical contact and consent to share their details with the research team was gained. The principal investigator also held an honorary contract with the service as a clinical team member so could approach service users directly.

The principal investigator phoned all potential participants to discuss the nature of the study and their involvement. Those who indicated interest were emailed a copy of the participant information sheet (PIS; Appendix A), informed consent form (ICF; Appendix B) and study advertising flyer (Appendix C). Those who were interested in taking part were screened by the principal investigator to ensure they met all the inclusion criteria. This was also openly discussed with clients to ensure eligibility. All participants were given at least 24 hours to decide whether they would like to take part in the study and to allow them the opportunity to discuss it with their support network. Participation was entirely voluntary, and no compensation was offered.

Power

Power calculations for SCED are based on the number of subjects, phases and data points per phase (Tanious & Onghena, 2019). Shadish et al. (2014) report that for a power of 0.8, nine subjects are required with at least 12 data points per phase. WWC guidelines are a rigorous standard for the assessment of SCED quality. WWC guidelines state that the standards require a minimum of five data points in a phase to meet ‘standards without reservations’ and at least three data points to meet ‘standards with reservations’ (Kratochwill et al., 2010; WWC, 2020). Previous SCEDs in obese populations have recruited samples of up to five participants (Abrahamsson et al., 2018; Sadeghi et al., 2010) so the current study

exceeds those figures. Furthermore, Barnard-Brak et al., (2021) demonstrated that baselines with six to seven data points yielded a bias of only around 5%. Therefore, a minimum of seven data points during baseline meets not only WWC criteria, but also sits well within wider literature on effect sizes.

Therapist

The principal investigator acted as the only therapist for the study. The therapist received training from the academic supervisor who devised the therapy manual and has extensive clinical experience of using polyvagal theory in therapy. Training took place over two one-hour sessions and comprised of information sharing and role play. Training also occurred throughout delivery of the intervention in weekly clinical supervision.

Ethics

The study was reviewed and approved by Royal Holloway University of London (RHUL) Research Committee (Appendix D). The study was reviewed and given favourable opinion by North West - Greater Manchester South Research Ethics Committee on 27/06/22 (22/NW/0178). The study was also approved by the NHS Health Research Authority (HRA), NHS Trust specific Research and Development (R&D), and RHUL Ethics Department. A non-substantial amendment was submitted on 25/10/2022 and approved on 03/11/2022. Approval documentation can be found in Appendix E.

Service User Consultation

Two experts by experience from Obesity UK were consulted on the PIS, ICF. Questions were co-produced for the visual analogue scales (VAS) and client feedback form. Their feedback was incorporated into the final versions of documents.

Design

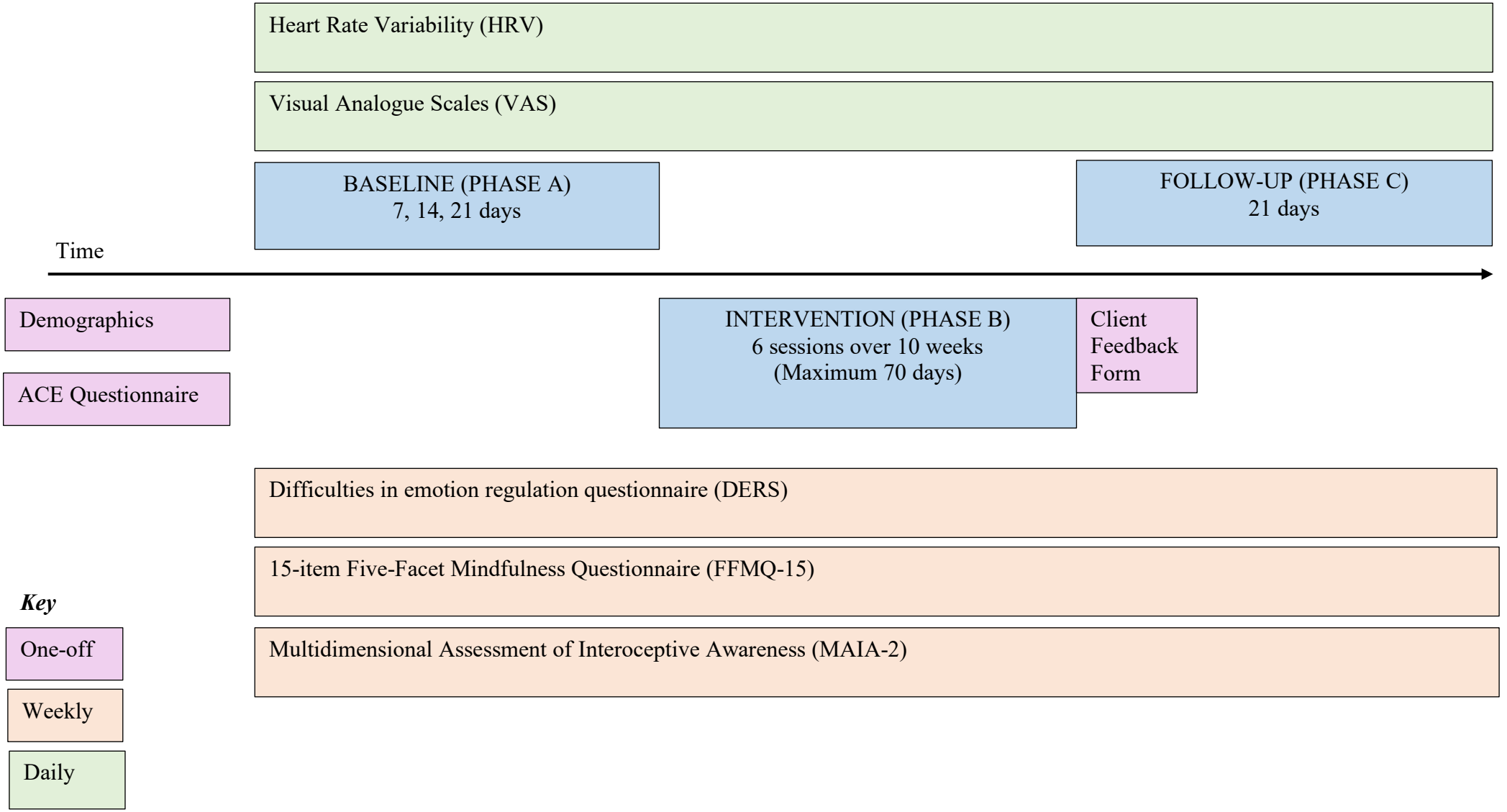
This study adopted a randomised multiple baseline within subjects SCED. This design was decided on as it allows participants to act as their own control and is suited to this

heterogeneous population, whilst maintaining experimental control (Morley, 2017). It is also a favourable design for the evaluation of novel psychological interventions as it provides insight into treatment related changes (Barlow et al., 2009). The design was nonconcurrent, meaning participants received the intervention as and when they became available over the six-month time period that the research was conducted. Participants were randomly allocated a baseline period of either seven, 14, or 21 days (phase A of design) using an online random number generator. Three baseline lengths were chosen as the recommended minimum to establish experimental control (Barlow et al., 2009; Kazdin, 2010; Kratochwill et al., 2010). These lengths were chosen to provide enough time to observe some stability in outcomes whilst not raising ethical concerns in terms of withholding treatment. The introduction of the intervention (phase B) started immediately after the individual's baseline period ended. The intervention was polyvagal theory informed therapy as described below. Outcomes were compared at the same stages across participants e.g., after six sessions of intervention, to monitor causal explanations. The intervention effect was measured through VAS and standardised measures.

A three-week follow-up period took place after the intervention (phase C). Participants completed daily and weekly outcome measures throughout all phases. This monitored whether treatment gains were maintained, and/or capture delayed treatment gains. An overview of study phases and collection of measures is presented in Figure 3.

Figure 3

Study Procedure and Data Collection



Measures

This study used four different types of outcome measures: idiographic, process, standardised, and an acceptability measure. A combination of idiographic and standardised measures were used to capture overlapping constructs related to body awareness and emotion regulation. The combination of types of measures was used as idiographic measures are more sensitive to change due to the highly subjective nature of such questions (Morley, 2017). On the other hand, standardised measures, although less sensitive to change, provide information on the individual's score compared to population norms. This is helpful for ratifying the outcomes against the literature for this population. All outcome measures were electronically completed and participants used their participant ID so that all data was anonymised at source.

Idiographic Measures

The primary outcome measures were VAS which are commonplace in SCED as target measures, are tailored to the individual, and reflect the content of an individual's experience rather than a construct (Chalkley, 2015; Morley, 2017). These measures asked participants three questions about body awareness, emotion regulation and a frequency count of an emotion regulation behaviour (Appendix F). Participants completed these measures daily throughout all phases. All questions allowed participants to rate their responses on a scale of 0 to 100. The final question asked participants to choose a specific behaviour they currently do in response to emotions that they would like to reduce over the course of therapy. This was decided at baseline stage and supported by the therapist. This question was framed as "Over the last 24 hours, how much have you…". This allowed participants to actively choose a specific and relevant behaviour aimed to increase participants' engagement with the measures and ensure the desired outcomes were personally meaningful. Participants' choices are presented in the results section.

Process Measure

The process measure was the first VAS question which asks “Over the last 24 hours, were you aware of your bodily sensations”. This question was chosen to measure body awareness, testing whether PVTT was having the predicted effect to support interoceptive sensibility. Daily VAS pertaining to body awareness provides insight into the variability of interoception (Höller et al., 2021).

Heart Rate Variability (HRV)

HRV was measured using the HRV4Training app which uses a method known as photoplethysmography (PPG), a light-based technology that records intervals between heart beats through blood flow. Participants were asked to measure HRV first thing every morning, before any daily stressors could impact recordings (Altini, 2015; Shaffer et al., 2014). This mobile app has been validated as an accurate measure of HRV comparable to traditional EEG recordings by the creators of the app (Plews et al., 2017) and independently in a recent review (Stone et al., 2021). HRV4Training app records activity over a one-minute time interval. According to the Task Force of the European Society of Cardiology and the Northern American Society of Pacing Electrophysiology (1996) recommendations, root mean square of successive difference (RMSSD) is the most accurate measure of vagus nerve mediated autonomic control of the heart. Although seemingly dated, these recommendations are widely used today to guide clinical applications of HRV (Ecker & Lykins, 2019; Shaffer & Ginsberg, 2017). RMSSD is a time domain measure. It is the square root of the mean of the sum of the squares of differences between normal-to-normal (N-N) intervals. RMSSD normally ranges from 0 - 250 milli seconds, with most people in the 30-80 range depending on age as well (Shaffer & Ginsberg, 2017). RMSSD is also less effected by breathing than high frequency (HF) or low frequency (LF) power variables and therefore is the variable that was used in this study as an accurate reflection of vagal tone (Shaffer & Ginsberg, 2017).

Standardised Measures

The following standardised measures (Appendix G-J) were administered.

The Adverse Childhood Experience (ACE) Questionnaire (Felitti et al., 1998) is a 10-item self-report questionnaire measuring childhood adversity. It is a validated and reliable measure used in large scale studies to predict risk of later life health problems (Dube et al., 2003). Generally a score of four or above, out of a possible 10, is considered to be clinically significant due to an increased risk of the development of health difficulties (Hughes et al., 2017). This measure was administered once, at the start of baseline.

The following standardised measures were administered weekly throughout baseline, intervention and follow up.

Difficulties in Emotion Regulation Scale (DERS; Gratz & Roemer, 2004) is a 36-item self-report questionnaire with statements reflecting six domains: nonacceptance of emotional response (α=.85), difficulties in adopting goal-directed behaviours (α=.89), difficulties in controlling impulsive behaviours (α=.86), lack of emotional awareness abilities (α=.80), limited access to emotion regulation strategies (α=.88), lack of emotional identification or clarity (α=.84). Higher scores indicate greater difficulty. The DERS has good test–retest reliability, adequate construct and predictive validity (Gratz & Tull, 2010). It has been shown to be sensitive to change in response to interventions that target emotion regulation (Gratz, et al., 2014; 2015). Instructions were modified to ask participants to focus on the last week. The DERS has also been used in studies to show an association with HRV (Berna et al., 2014) and validated for use with obese adults demonstrating a Cronbach's alpha for the total score of .87, and .74–.89 for the subscales (Gianini et al., 2013).

Multidimensional Assessment of Interoceptive Awareness (MAIA-2; Mehling et al., 2018) assesses eight aspects of interoceptive awareness through a self-report including noticing (α=.64), not distracting (α=.74), not worrying (α=.67), attention regulation (α=.83),

emotional awareness (α=.79), self-regulation (α=.79), body listening (α=.80) and trust (α=.83). Overall score is calculated by averaging all items. Items are scored on a scale of 0-5 and higher scores indicate greater interoceptive awareness. The instructions for MAIA-2 were adapted to ask participants to focus on the past week which helps to overcome issues with memory bias (Ebner-Priemer & Trull, 2009) and allow for weekly administration. MAIA has been used in obese populations (Willem et al., 2021).

The *15-item Five-Factor Mindfulness Questionnaire* (FFMQ-15; Baer et al., 2008) measures interoceptive awareness through the lens of mindfulness. It is a self-report questionnaire across five dimensions of mindfulness including observing (α=.64), describing (α=.80), acting with awareness (α=.68), non-judging of inner experience (α=.76) and non-reactivity to inner experience (α=.66). This scale is sensitive to change and consistent in terms of factor structure with the longer 39 item version (Baer et al., 2008; Gu et al., 2016). Participants respond on a scale of 1-5 and higher scores indicate greater mindfulness abilities. This measure is commonly used in samples of people with heavier body weight and complements MAIA (Willem et al., 2021).

Measure of Acceptability

The Client Feedback Form (Appendix K) was administered at the end of intervention and is based on Sekhon et al.'s (2018) theoretical framework of acceptability (TFA) for health interventions. The generic TFA-based questionnaire (Sekhon et al., 2022) was adapted so that questions were relevant to the intervention. This includes six items: affective attitude (how they felt about the intervention), burden (how much effort it required), perceived effectiveness (how likely it is to make a difference), intervention coherence (how well they understand the intervention and how it works), self-efficacy (their perception that they can make suggested changes), opportunity costs (how much it interfered with other priorities). The item of ethicality, the moral consequences of the intervention, was not relevant to this

study and therefore was omitted. Items are rated on a five-point Likert scale. A mean score of the six items and a mean score for the seventh item, which assesses general acceptability, was calculated. Higher scores indicate higher acceptability. Despite this measure being relatively new and therefore, its psychometric properties have yet to be rigorously evaluated, it was chosen due to its theory-driven multidimensional approach that allows for tailoring to the specific intervention.

Procedure

Randomisation and Initial Appointment

When participants were screened as eligible and agreed to take part in the study, they attended an appointment with the principal investigator, who also acted as the therapist, and completed the ICF (Appendix B). The principal investigator randomly allocated participants to a baseline period using a computerised random number generator. Participants were informed of their baseline period during this initial consent and set up appointment. All appointments took place virtually using the Attend Anywhere platform.

In this appointment, which took up to one hour per participant, baseline measures were completed by the participant. They were given a code to download the HRV app and took their first recording with the support of the therapist. They were advised that they should take daily HRV recordings first thing in the morning to ensure consistency in their recordings and before the impact of daily stressors. Participants consented to share their data with the therapist as the 'coach' in app settings, which meant data was directly shared to the therapist's online portal. Participants then completed the VAS which included a therapeutic conversation around their chosen behaviour for the final question of the VAS. Participants were supported to choose a behaviour that occurred at least daily, and something they felt personally motivated to change. An understanding about the presentation of this behaviour was established between the participant and therapist. Participants then completed the

weekly measures. Finally, the first therapy session was scheduled based on their allocated baseline period.

Baseline Phase

Throughout the baseline phase, participants were asked to complete daily and weekly measures. Baseline periods were considered to be an acceptable length as it was expected that each participant would have a minimum of seven baseline data points. This meets WWC "standards without reservations" criteria (Kratochwill et al., 2010; WWC, 2022). Although some SCED literature requires stabilisation of outcomes before intervention commences, this was not considered to be practical within this study and therefore baseline lengths were pre-determined. Participants were expected to complete between seven and 21 idiographic data points and one to three standardised data points during this phase.

Intervention Phase

Participants completed six sessions of online video therapy over a maximum ten-week period. As all participants act as their own control in SCEDs, variation in the delivery of the treatment manual is acceptable (Kratochwill et al., 2010). Adaptations and flexibility in the treatment manual were made on a case-by-case basis in collaboration between the therapist and participant, with guidance from supervision.

If the participant had given consent, therapy sessions were audio recorded. Alongside indication on the ICF, the therapist checked for verbal consent at the beginning of each session before initiating recording. Most participants attended weekly sessions for the first four sessions and then met on average fortnightly for the final two sessions. This was decided between therapist and participant to provide increased time between the final sessions for participants to practice and implement strategies in their daily lives. It was expected that participants would complete up to 70 idiographic data points and 10 standardised data points during the intervention period.

Communication between participants and therapist occurred mostly over email or text. The therapist sent emails with links to videos and files (e.g., ANS tracker/polyvagal ladder; see Appendices L-N) following sessions. Participants could contact the therapist over email to change appointment times if needed. There was no communication outside of sessions in the form of prompting on homework or responding to therapy-related questions. Communication was limited in all cases to appointment scheduling and prompts related to outcome measure completion. The frequency of communication outside of sessions was not predefined.

After the final therapy session participants were asked to complete the client feedback form.

Follow-up Phase

Participants continued to complete daily and weekly measures for up to three weeks after intervention. This allowed for measurements of maintenance of change. There was no specific homework setting at the end of session six, but more of a therapy blueprint which included a plan about which techniques and learnings participants would be taking forward into their lives. This was agreed not as a continuation just for the follow up phase but as a continuation and integration into their lives beyond the study. Participants were expected to complete up to 21 idiographic data points and three standardised data points during this phase. All participants were asked whether they would like to receive a summary of their outcomes and a copy of the study findings. Participants were discussed with the service's clinical psychologist to decide whether they required any further input from the clinical team after completion of follow up.

Intervention

The therapy manual (Appendix L) was designed by Dr Katie Ashcroft, clinical tutor and clinical psychologist, who is experienced with using polyvagal theory in therapy.

Relevant clinicians in the field including Dr Esme Banting, senior clinical psychologist in specialist weight management and bariatric surgery, were consulted on the appropriateness of the intervention for use with obese populations.

All sessions were delivered using video call with a NHS trust approved online platform, Attend Anywhere. Sessions mostly consisted of reviewing homework tasks, reviewing progress, discussion of VAS scores, ANS psychoeducation, practicing of strategies and homework setting. All work was collaborative. Sessions took between 50-60 minutes and timings of sessions were decided on a week-to-week basis between the therapist and participant based on mutual availability. Participants were encouraged to take notes in sessions, both of session content and a written agreement of homework tasks.

The intervention consisted of three broad stages:

Session One to Three

Introduction to polyvagal theory: conceptual socialisation to the polyvagal understanding of the ANS and the meaning of this in relation to the participant's presenting difficulties.

Sessions Three to Five

Exercises to regulate: teaching and practice of regulation strategies. Continual monitoring of in session experience and out of session experimentation.

Session Six

Summarising and therapy blueprint.

Homework consisted of practicing ANS regulation strategies and took on a flexible cumulative approach such that any helpful techniques introduced from session one would continue to be practiced each week alongside any new techniques. This meant that by session five, many participants would have at least five homework tasks. Homework tasks included

breathing exercises, body scans and walking with some only taking a little as one-minute (e.g., eyebrow wagging).

The therapist received weekly clinical supervision provided by the academic supervisor who devised the treatment manual and is experienced in providing polyvagal informed therapy. Weekly supervision consisted of case discussion, formulation, adherence to the therapy manual and grounding clinical work in polyvagal theory. This was facilitated through clinical discussion and listening to therapy session recordings. Ad hoc clinical supervision was provided by the service's clinical psychologist when required. For example, when questions about adaptations for people living with obesity came up.

Treatment Fidelity

Treatment fidelity was monitored in two ways. The therapist shared audio recordings of sessions in weekly supervision to monitor adherence to the core principles of the therapy manual and to tune therapist skills and style. Secondly, 10% of audio recordings of sessions were rated by the clinical supervisor using an adapted version of the Revised Cognitive Therapy Scale (CTS-R; Blackburn et al., 2001b). This can be found in Appendix O. The academic supervisor, also author of the therapy manual, has over 15 years of experience with CTS-R. This adapted PVTT rating scale uses six validated items from the CTS-R: agenda setting, feedback, collaboration, pace, interpersonal effectiveness, and homework setting (Blackburn et al., 2011a). Three items have been added particular to the PVTT manual: psychoeducation, skills teaching and review of tracking. As with the CTS-R, the Dreyfus scale (Dreyfus, 1989) is used for denoting competence. Depending on the session, it may be appropriate to omit psychoeducation or reviewing tracking and in such cases these can be marked as not applicable. Competence is denoted by 50% of a variable possible total score.

Data analysis

Visual Analysis

VAS data on body awareness, emotion regulation and participants' chosen behaviour was analysed using visual analysis and Tau-U statistical analyses. HRV data was also analysed in the same manner. Kratochwill et al. (2010) and WWC (2017) set out four steps that consider six features for carrying out visual analysis. The first step is assessing stability in the baseline phase. In Tau-U analysis, baselines were analysed for trend, and if trend was present, this was controlled for in the analysis to increase accuracy in comparison of phases (Manolov et al., 2014). The second step involves evaluating the within-phase patterns using the six features outlined below. The third step consists of assessing each phase compared to the adjacent phase to evaluate whether there is an 'effect' from the manipulated independent variable. In this study, an effect is a predicted change being demonstrated in the data between baseline with intervention phase and intervention phase with follow up. In this step, the expected latency of change must be considered based on the theoretical understanding and predictions of the intervention (Kazdin, 2019). Given that we are not expecting a short latency, i.e., an immediate effect from the start of intervention like one would expect from some medications or behavioural interventions, the immediacy of the effect will not be examined closely in this analysis, though the timing of effect was commented on where evident. The final and fourth step is to assess information across all stages to ascertain indications of an effect. In order for a causal relationship to be established, replication of effect should be documented at least three times across different baseline lengths (Horner et al., 2005; Kratochwill et al., 2010).

The six features, outlined by WWC, include level, trend, variability, immediacy of the effect, overlap and consistency of data patterns across similar phases (Kratochwill et al., 2010). Two features are less relevant for this study. Immediacy of effect compares the final

three data points of one phase with the adjacent three data points in the next phase. The immediacy of effect is not measured here as a rapid effect following introduction of the intervention is not expected. Secondly, consistency of data patterns across similar phases is not relevant since there are no repeated phases. Although phase A and C are similar in the absence of intervention, phase C will be affected by the intervention during phase B and therefore is not directly comparable to A.

Due to the variability in the data, which is expected due to the regularity of data collection in SCEDs, medians have been taken to display measure of central tendency (Morley, 2017). This is to overcome difficulties with the average (mean) which is skewed by extreme points. In this case, the broadened median has been chosen to represent the level of central tendency (BMed; Morley, 2017; Rosenberger, & Gasko, 1983). A trend is considered as a systematic shift in the central tendency over time, and was measured here by running medians (Morley, 2017).

The data was then subjected to Tau-U statistical analysis to assess the proportion of overlap between phases using Tau-U calculator (www.singlecaseresearch.org/calculators/tau-u). Rather than only focusing of measures of central tendency, Tau-U takes into consideration all the data within a phase, subtracting the percent of overlapping data from the percent of nonoverlapping data (Parker et al., 2011). A Tau-U score equal or close to one indicates no overlap which supports causal inferences to be made from the intervention, making it a suitable analysis for SCED (Morley, 2017). Tau-U allows for changes between phases to be detected with objectivity when they might not be discernible from visual analysis, reducing the likelihood of a Type II error (Morley, 2017). Tau-U controls for positive trends in the baseline which mean that the participant could have improved without the intervention which supports valid conclusions about the cause of change (Parker et al., 2011). Therefore, phase A was compared to phase B (A x B) to assess for improvements in idiographic data following

intervention onset. Phase B was compared to phase C (B x C) to assess for maintained or further changes following withdrawal of the intervention. Given that phase C is contaminated by the effects of B, no comparisons were made between phase A and phase C and there is a lack of consensus on whether non-adjacent phase comparison is valid (Parker & Vannest, 2012). Comparisons between phase A and the combination of B and C (A x [B+C]) were made to assess overall treatment effects compared to baseline. In instances where there were three or more demonstrations of an effect on individual VAS, data was combined across participants to yield a single omnibus Tau-U effect, using weighted averages. This reflects the extent of data non-overlap across participants for that VAS.

Analysis of Standardised Data

Standardised measures assessed participants' interoception (MAIA-2; FFMQ-15) and emotion dysregulation (DERS) weekly throughout all three phases of the study. It was hypothesised that following the intervention, participants would report increased interoception and decreased emotion dysregulation.

Standardised data was analysed by assessing reliable change (RC) and clinically significant change (CSC). RC reflects a statistically significant change in scores that cannot be accounted by measurement error (Jacobson & Truax, 1991). Jacobsen and Truax (1991) propose that reliable change index (RCI) can be calculated using the following equation: RCI = (pre-treatment score – post-treatment score) / SE_{diff}.

SE_{diff} refers to the standard error of difference, calculated as $\sqrt{2 \times SEM^2}$. Where SEM refers to the standard error of measurement which was calculated as standard deviation (SD) x $\sqrt{(1-r)}$. In this formula, r refers to the reliability of the measures. Cronbach's alpha (α) of the internal reliability of the measures was used as an appropriate indicator as it reduces the SEM (Morley, 2017). Where possible, α was taken from the validation of the measure in

relevant population. Reliability and normative sample statistics are presented in Table 1. An RCI of +/-1.96 can be considered as statistically reliable change (Jacobsen & Truax, 1991).

Pre-treatment scores were calculated as an average of baseline scores. Post-treatment scores were the final score of the intervention phase and, if they completed it, the final follow up score.

Table 1

Reliability and Normative Sample Statistics to Calculate RC and CSC

Measure	Cronbach's alpha (source)	Non-clinical norms Mean (SD; Source)	Criterion for CSC
DERS	.87 (Gianini et al., 2013)	77.9 (20.72; Female only; Grazt & Roemer, 2004)	B
MAIA-2	.64 (Mehling et al., 2018)	2.06 (0.90; Mehling et al., 2018)	B
Noticing	.74	2.06 (0.80)	
Not-Distracting	.67	2.52 (0.85)	
Not-Worrying	.83	2.84 (0.86)	
Attention Regulation	.79	3.44 (0.96)	
Emotional Awareness	.79	2.78(1.01)	
Self-Regulation	.80	2.20 (1.17)	
Body Listening	.83	3.37 (1.11)	
Trust			
FFMQ-15	.76 (Beshai et al., 2022)	50.38 (6.39; Beshai et al., 2022)	B

If RCI was reached, CSC was calculated. Jacobsen and Truax (1991) propose three criteria that can be used to establish CSC. Criterion A assesses whether the individual's score moves more than two SD from the clinical group mean. Criterion B is used to assess when the individual's score moves within two SD of the non-clinical population mean. Finally, criterion C, the least arbitrary, establishes whether the individual's score moves closer to the mean of the non-clinical population than to the mean of the clinical population. For the purposes of this study, criterion B was used throughout as only normative data from a non-clinical population was available since these measures are not symptom measures, nor do they have thresholds for

what is deemed ‘clinical’ vs. ‘non-clinical’. Furthermore, we would not be expecting participants to move into a ‘non-clinical’ range from the intervention as there is not a defined ‘clinical’ population.

Acceptability

Descriptive statistics were calculated for the individual items on the acceptability questionnaire and a general acceptability score. Two items, ‘burden’ and ‘opportunity and costs’ are reverse scored. Qualitative data collected from additional questions regarding the experience of the intervention was summarised.

Results

For confidentiality purposes, participants are referred to by a randomly allocated letter. Some personal details have been omitted to protect the anonymity of participants. Results are presented in four sections: descriptive participant and intervention information, visual analysis of SCED data and process measures, standardised data and acceptability.

Data Cleaning

Missing data in the analysis has been treated as missing at random (MAR; WWC, 2017). HRV data was cleaned so that only optimal and good ratings of recordings were used in the analysis. Proportions of missing and cleaned data are reported for each participant.

Participants

The final sample for analysis consisted of nine participants with a mean age of 42.1 (SD = 9.8). All participants were white, seven of which were white British and two were white African. Participant demographic and clinical information is presented in Table 2. Four participants had mental health diagnoses including depression, emotionally unstable personality disorder and anxiety.

Treatment Duration and Retention

Eight out of nine participants received six sessions of PVT. One participant (PtD) completed five out of six sessions, missing the final intervention session following withdrawal from the study. No reasons were given for withdrawal. In total, 54 sessions of therapy were offered across nine participants and 53 sessions were attended (98.15%) indicating high treatment retention. Sessions were on average one hour long meaning that those who completed six sessions of intervention received six hours of therapy and participant D received five hours. Prompting outside of sessions via text message or email related to completing measures only. There was no therapeutic input outside of session time. Participants completed intervention sessions across different intervention phase lengths based

on agreed scheduling between therapist and participant. Phase lengths are reported alongside VAS data.

Treatment Fidelity

Eight participants consented to having their sessions audio recorded. Two sessions of those who consented were not recorded due to technology difficulties. Treatment fidelity was monitored through weekly clinical supervision between the academic supervisor and therapist. In these sessions, audio recording clips were shared and discussed to ensure adherence to the treatment manual and theoretical stance. This was assessed on a case-by-case basis so that the intervention was tailored to each participant's needs. This flexibility in delivery of the manual is suitable for the SCED.

Out of 45 recorded sessions, 10% (n = 4) full sessions were rated by the academic supervisor for treatment fidelity using an adapted version of the CTS-R (Blackburn et al., 2001; Appendix O). Recordings were chosen at random using a random number generator. All reviewed sessions met competence and adherence to the manual, denoted by meeting the minimum 50% of a variable possible total score (M = 57.7, SD = 8).

Table 2

Participants Demographic and Clinical Information

Pt	Sex	Age	Ethnicity	Medication	Comorbidities	Previous psychological therapy (type and year/number of sessions if known)
A	F	50	White, African	Famotidine 20mg Levothyroxine 150mcg Metformin 2000mg Mirtazapine 15mg Montelukast 10mg Omeprazole 40mg Pregabalin 200mg Prochlorperazine 15mg Quetiapine 100mg 3x night, 25mg 5x daily Venlafaxine moderate release 225mg Fostair Buprenorphine patch 5mcg Avamys nasal spray 27.5mcg spray Etoricoxid 50mg	Emotionally unstable personality disorder (EUPD) Type 2 Diabetes (T2DM) Hyperthyroidism Gastro-oesophageal reflux disease (GORD) Asthma Emphysema Bilateral hip dysplasia Obstructive sleep apnoea	MBT group 2019 18-month CBT Years unknown, 4-5 times 6-10 sessions each
B	F	52	White, British	Sertraline 150mg Mirtazapine 7.5mg	Depression	Missing
C	F	43	White, British	Sertraline 50mg; Increased to 100mg midway through intervention phase	Depression	CBT 2006 6 sessions ACT 2022 4 sessions
D	F	38	White, British	Sertraline 50mg Salbutamol inhaler	Obstructive sleep apnoea	None

				Salamol 100mcg Ferrous fumarate 210mg		
E	F	28	White, British	None	None	None
F	F	27	White, British	None	Anxiety Depression Non-alcoholic fatty liver disease (NAFLD)	ACT 2022 5 sessions
G	F	42	White, British	Ramipril 2.5mg once daily Tranexamic acid pm (4x per day PRN)	Hypertension	None
H	F	55	White, African	Levothyroxine 125mcg daily Bisoprolol 1.25mg daily Pregabalin 5mg daily Aspirin 75mg daily Omeprazole 20mg daily Folic acid 5mg daily Vitamin d stexerol-D3 - 2000 IU	Gastric band 2010 (not inflated, awaiting removal) Fibromyalgia Hyperthyroidism Atrial arrythmia Connective tissue disease Obstructive sleep apnoea (diagnosed during follow up)	None
I	F	44	White, British	Sertraline 100mg	Gastric sleeve 2020 Obstructive sleep apnoea	CBT 2012 14 sessions CBT 2016 52 sessions ACT 2022 7 session

Note. Pt = participant; F = female; PRN = pro re nata, medication taken as needed; mg = milligrams; mcg = microgram; IU = international unit

MBT = mentalisation based therapy, CBT = cognitive behavioural therapy, ACT = acceptance and commitment therapy.

Analysis of SCED data

The Single-Case Reporting Guideline in BEhavioural Interventions (SCRIBE; Tate et al., 2016) was followed in the reporting of SCED results. Participants completed daily VAS asking about body awareness, emotion regulation and frequency of a chosen behaviour. It was hypothesised that as a result of the intervention, VAS scores on body awareness and emotion regulation scores would increase and chosen behaviour would decrease compared to baseline. The next section outlines VAS data for each participant, beginning with a short description of therapeutic engagement and any other factors that were relevant during the study period such as personal circumstances or extraneous events. Visual analyses are summarised alongside Tau-U statistical analysis. Phases with at least three data points were included in analysis as these meet WWC 'standards with reservations' (Kratchowill et al., 2010). HRV has varying phase lengths compared to VAS due to data cleaning which means number of data points per phase were reduced.

There are some instances where broadened medians and running medians are not discernible from the graphs presented below. This occurs in instances where the values are matched with raw data which is represented by a solid line, or the values are equal to 0 and therefore hidden by the axes. Raw data is depicted by a solid line with square marker. Intervention sessions are depicted by a green triangle marker. An overview of key terms and the associated graphical representation in visual analysis is presented in Table 3. Graphs depicting variability in the form of trended range can be found in Appendix P.

Table 3

Overview of Key Terms and Graphical Representation in Visual Analysis

Type of measure	Key Term	Explanation	Number of data points	Graphical representation
Central Tendency	Broadened median (BMed)	Odd numbered series: average of the three middle values Even numbered series: average of the four middle values	5-12	Dashed line
Central Tendency	Broadened median (BMed)	Odd numbered series: average of the middle five values Even numbered series: average of the middle six values	>13	Dashed line
Trend	Trend	Running median of 2 successive points (RM2)	<6	Dotted line
Trend	Trend	Running median of 3 successive points (RM3)	6-10	Dotted line
Trend	Trend	Running median of 5 successive points (RM5)	>10	Dotted line
Variability	Trended Range	Changes in variability over time indicated by lines between the two maximum and two minimum data points in each half of the phase	>3	Solid line with diamond marker

As visual analysis can be subjective, it was agreed that a third of the VAS and HRV graphs would be reviewed by a second reviewer and visual analysis discussed to ensure objectivity of the principal investigator when approaching the data. Three participants were independently subjected to visual analysis and then the two reviewers (the principal investigator and another trainee clinical psychologist) reviewed level of agreement across four features of analysis (level, trend, variability, overlap). Overall, there was 93.75% agreement. Areas of non-consensus were discussed and agreements were incorporated into the analyses below.

Participant A (PtA)

PtA scored eight out of a possible 10 on the ACE questionnaire (see Appendix Q for table of scores) indicating a high level of ACEs. She was randomised to a three-week baseline period. She chose "Over the last 24 hours, how often have you reached for comfort food?" as her chosen behaviour question.

PtA completed 21 days of baseline phase with 48 VAS data points across three questions (76.19% completion), 53 days of intervention phase, with 101 data points (63.52% completion rate) and 16 days of follow up, with 33 data points (68.75% completion rate).

PtA described hyperactivity of her sympathetic state and a history of substance misuse to regulate. PtA found that giving herself permission to eat counteracted a learnt restriction mindset and enabled her to have a healthier relationship with food, nourishing her body. This transferred onto her ability to give herself permission to look after her nervous system through the PVTT techniques. In particular, she found six breaths a minute and the closed mouth cooperative smile helpful in regulating sympathetic activation. The smile also gave her permission to 'reset' if she had been engaging in unwanted emotion regulation techniques such as displaying anger towards others. Therapy worked on building her portfolio of 'ventral vagal activities' that supported a sense of safeness and soothing.

Visual and TAU-U Analysis

In terms of body awareness, there was variable baseline data with no discernible trends, which was confirmed by statistical analyses (Tau-U = .13, p = .50). There was a considerable drop in body awareness following commencement of the intervention, followed by an upward trend showing increased body awareness following session three which coincides with ANS tracking for homework. This is combined with reduced variability following session four. Despite a change in central tendency from baseline to intervention, there was no significant difference in overlap between these phases (Tau-U = .11, p = .52). The positive trend from session three continues and sustains throughout follow up. There was a significant difference between intervention and follow up phases (Tau-U = .52, p = .01) which could reflect improvements noted from session four.

For emotion regulation, there was a downward trend in the baseline which was corrected for in Tau-U analyses. Though there are more fluctuations in scores during intervention phase, emotion regulation follows a similar pattern to body awareness showing an upward trend following session three which coincides with the introduction of self-reported effective regulation strategies (cooperative smile). Non-overlap analyses demonstrate a significant difference between baseline and intervention (Tau-U = .44, p = .01). There is a clear upward trend towards the end of the intervention phase which continues into the initial stage of follow up phase. This is supported by Tau-U which confirms a significant difference between intervention and follow up (Tau-U = .45, p = .02) and an overall significant difference between baseline compared to intervention combined with follow up (Tau-U = .53, p < .001). This suggests an intervention effect for emotion regulation.

For her chosen behaviour, comfort eating, there is a U-shaped trend during baseline, demonstrating the high variability of the data which would be expected for this kind of

behaviour. There are marked fluctuations throughout intervention though an overall slight downward trend and a decrease in central tendency compared to baseline. This is supported by Tau-U (Tau-U = -.42, p = .02). There is considerably less variability in follow up, with lower scores maintained throughout apart from one spike. This is reflected in the considerably lower central tendency in follow up, and change between intervention and follow up is confirmed by statistical analysis (Tau-U = -.77, p < .001). The combination of intervention and follow up compared to baseline shows a significant reduction in comfort eating (Tau-U = -.53, p < .001). This suggests the intervention has significantly reduced the frequency of comfort eating.

Both body awareness and emotion regulation have an extreme low score as the final data point which could reflect the participant's reaction to their state benefits being withdrawn which she reported at the end. Interestingly this does not coincide with an increase in comfort eating suggesting other emotion regulation strategies may have been employed during this period.

Overall, VAS data suggests the intervention supported a significant increase in body awareness, emotion regulation and reduction in comfort eating frequency. Treatment gains were maintained for follow up.

During HRV data cleaning, 33/83 raw data points were removed for poor quality signal. There appears to be an upward trend following session four, which coincides with the introduction of more emotion regulation strategies that may have impacted HRV. However, there are notably less data points between session four and five which may overlook actual day-to-day variability and inflated trend. Visual inspection of central tendency reveals little change between phases which was confirmed by statistical analysis (Tau-U = -.08, p = .67).

Figure 4.1

Participant A Raw VAS Data for Body Awareness

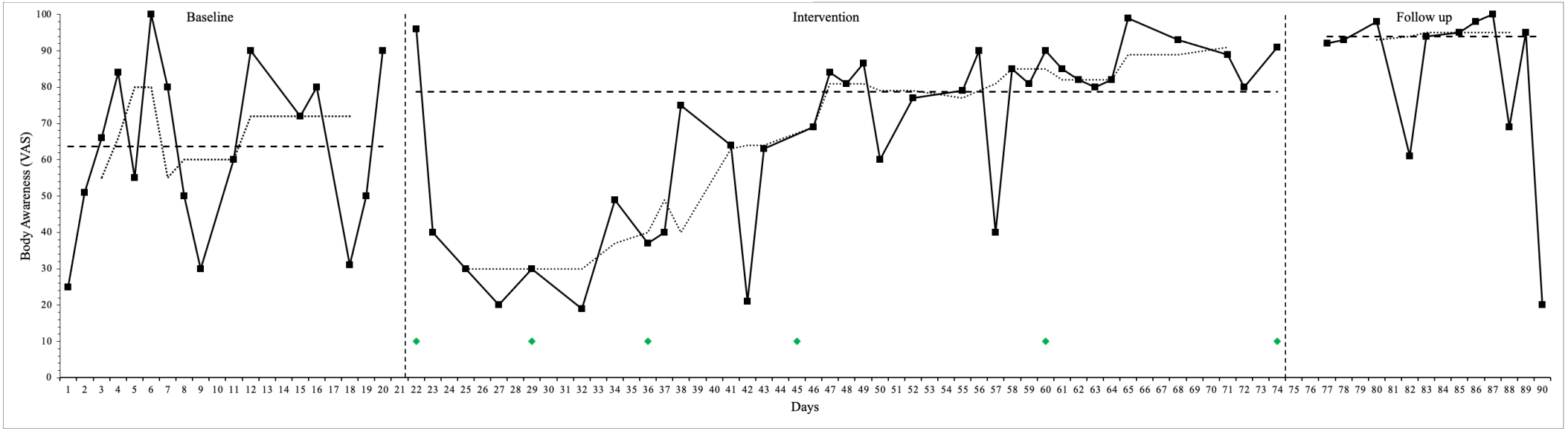


Figure 4.2

Participant A Raw VAS Data for Emotion Regulation

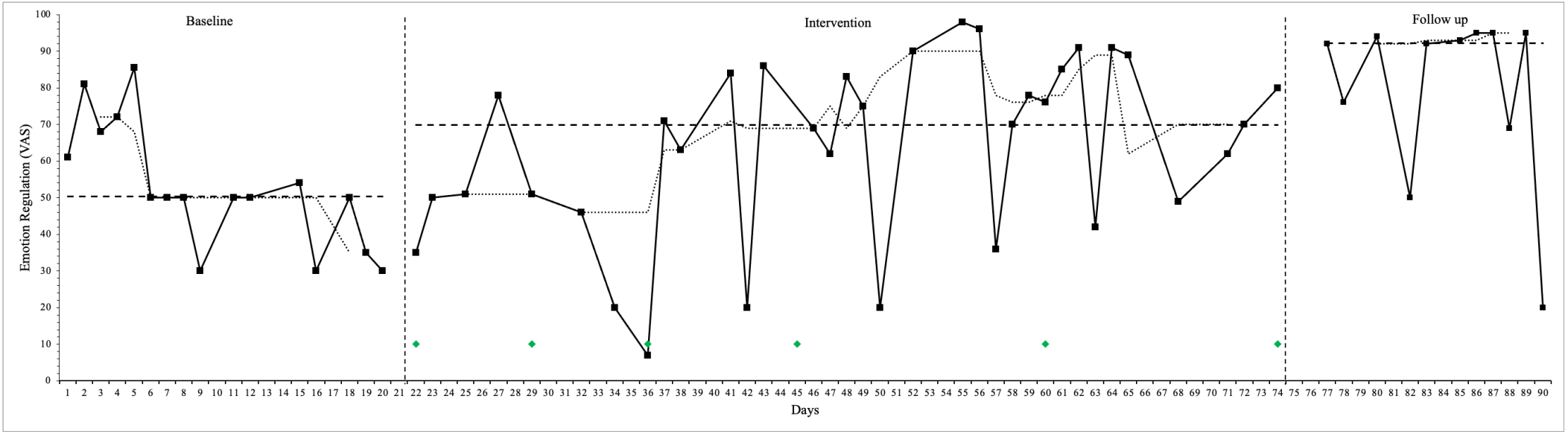


Figure 4.3

Participant A Raw VAS Data for Chosen Behaviour

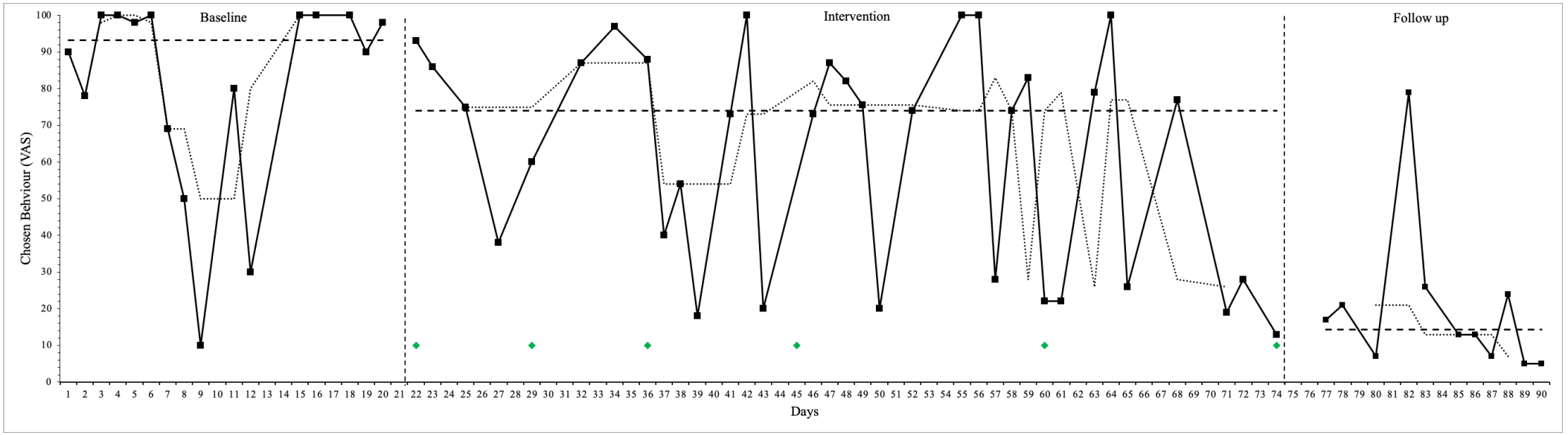
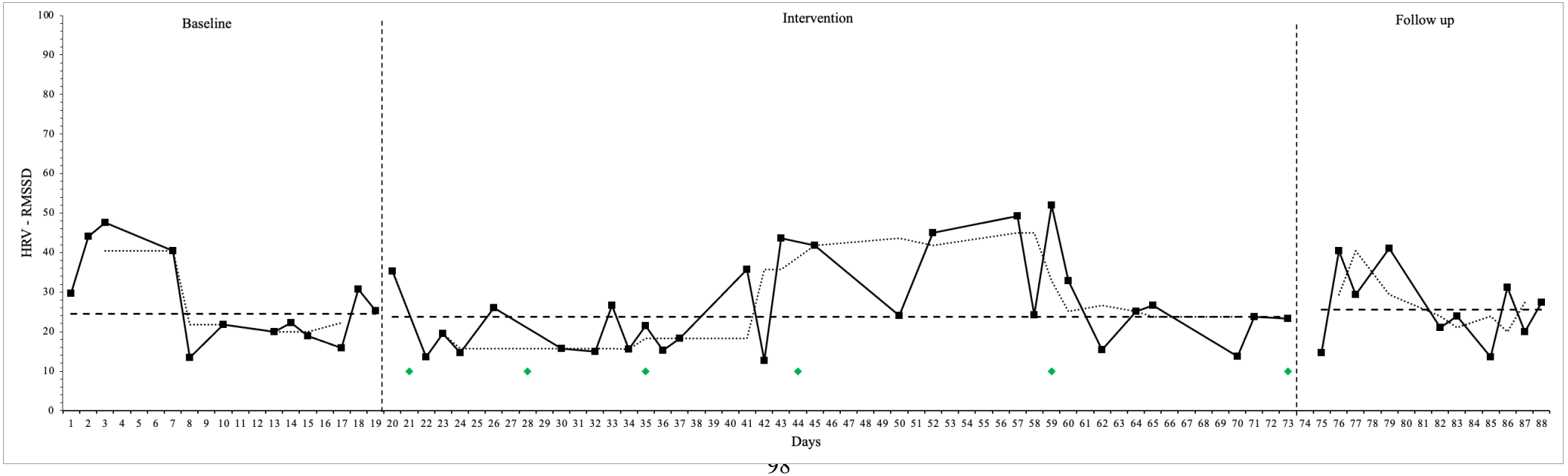


Figure 4.4

Participant A Raw Data for HRV - RMSSD



Participant B (PtB)

Participant B scored 4 on the ACE questionnaire. She chose "Over the last 24 hours, how much have you emotionally eaten?" as her target behaviour. Participant B was randomised to a three-week baseline period.

PtB completed 21 days of baseline phase with 36 VAS data points across three questions (57.14% completion), 59 days of intervention phase, with 80 data points (45.20% completion rate) and 12 days of follow up, with 21 data points (58.33% completion rate).

PtB reported difficulties implementing strategies between sessions which was linked to high work and family stress, and low self-worth which fed into a belief that she was not worthy of looking after herself. These were perpetuated by her experience of depression that meant she struggled with avolition. She most struggled with a sense of 'yo-yo-ing' between sympathetic activation and dorsal vagal which she described as an 'emotional marathon'. She found it extremely challenging to tune into her bodily signals due to intense feelings of shame and disgust about her body. Following session five, the participant partially disengaged for a period of time from the intervention due to a period of illness and brief hospitalisation. She was also undergoing investigations for possible breast cancer during this period. This resulted in a reported lack of practicing techniques, a large gap between session five and six (three weeks) and a considerable amount of missing data in this period.

Visual and TAU-U Analysis

There appears to be a downward trend during baseline for body awareness suggesting that this decreased through the three weeks of baseline. This was confirmed by statistical analysis (Tau-U = -.50, p = .02) and corrected for in further analyses. This downward trend is sustained through most of the intervention phase, with reduced variability compared to baseline. There is a slight upward trend following session five, though it is difficult to draw conclusions from this due to missing data. It is possible that her physical ailments could have

impacted her sense of bodily signals and/or willingness to attend to these rather than the intervention. There was a significant difference between intervention and follow up phase (Tau-U = .77, $p < .001$) such that body awareness increased.

There does not appear to be any trend in baseline data for emotion regulation, which was confirmed by statistical analysis. There is a reduction in central tendency between baseline and intervention for emotion regulation which is confirmed by statistical analysis (Tau-U = -.65, $p < .01$). There is an upward trend from session five that indicates an increase in emotion regulation that is sustained through follow up. This reversal between phases is supported by statistical analysis, as there was a significant increase in emotion regulation between intervention and follow up (Tau-U = .85, $p < .001$). The combination of intervention and follow up showed a significant reduction in emotion regulation scores compared to baseline (Tau-U = -.48, $p = .02$).

There is high variability for emotional eating throughout baseline. There is a clear increase in central tendency between baseline and intervention with increased variability at first, followed by a reduction in variability from session three though a continued reported high frequency. There was a significant increase in emotional eating between baseline and intervention (Tau-U = .38, $p = .05$) though no differences between other phases. There seems to be a reduction in frequency toward the end of the intervention and in the first week of follow up though it is not possible to draw conclusions from this due to the high amount of missing data during this period.

Overall, PtB showed changes to her body awareness between intervention and follow up, but it is difficult to draw conclusions on the impact of the intervention on these changes due to her physical health changes at the time. Emotion regulation changed in the opposite direction to hypotheses following intervention introduction and reversed for follow up. Although combination analyses confirm hypotheses, these should be treated with caution.

Similarly, emotional eating changed in the opposite direction to hypotheses. It could be that for this participant, increased attention on emotions and behaviours led to dysfunctional behavioural changes.

During HRV data cleaning, 23/61 data points were removed for poor quality signal. Visual inspection of central tendency, trend and variability of the data reveal little pattern which was confirmed by statistical analysis.

Figure 5.1

Participant B Raw VAS Data for Body Awareness

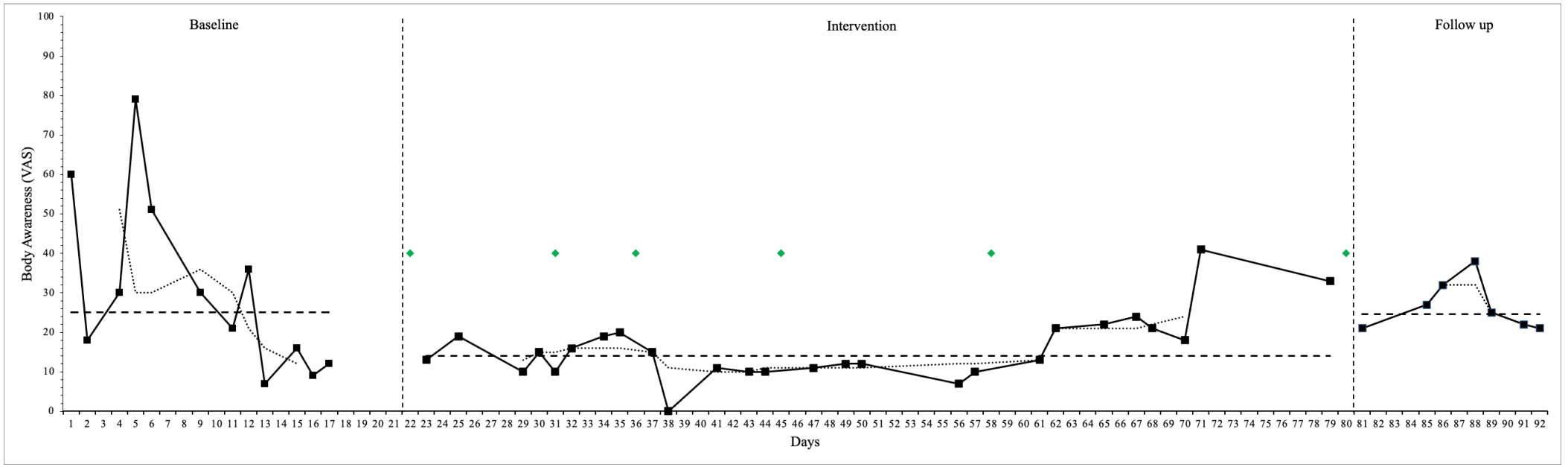


Figure 5.2

Participant B Raw VAS Data for Emotion Regulation

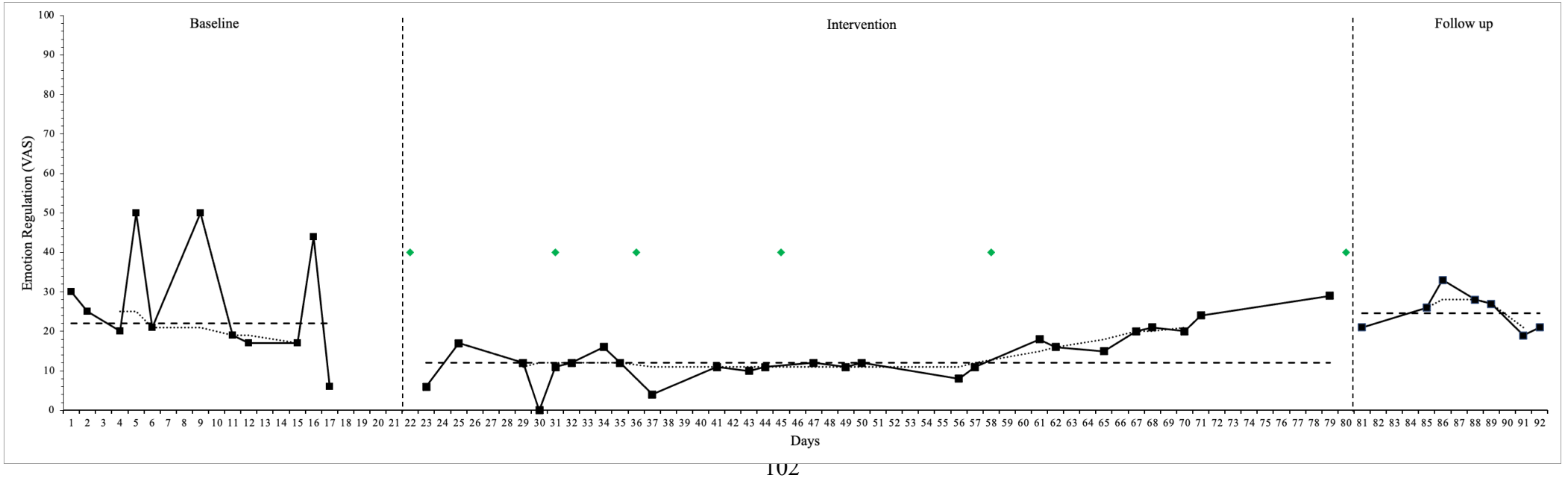


Figure 5.3

Participant B Raw VAS Data for Chosen Behaviour

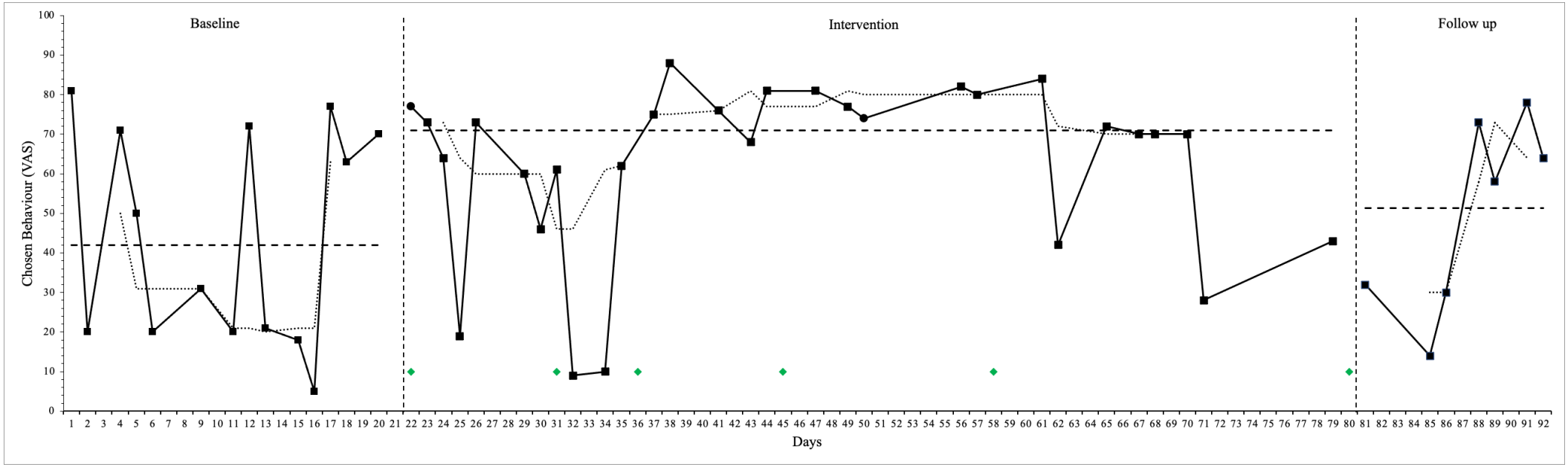
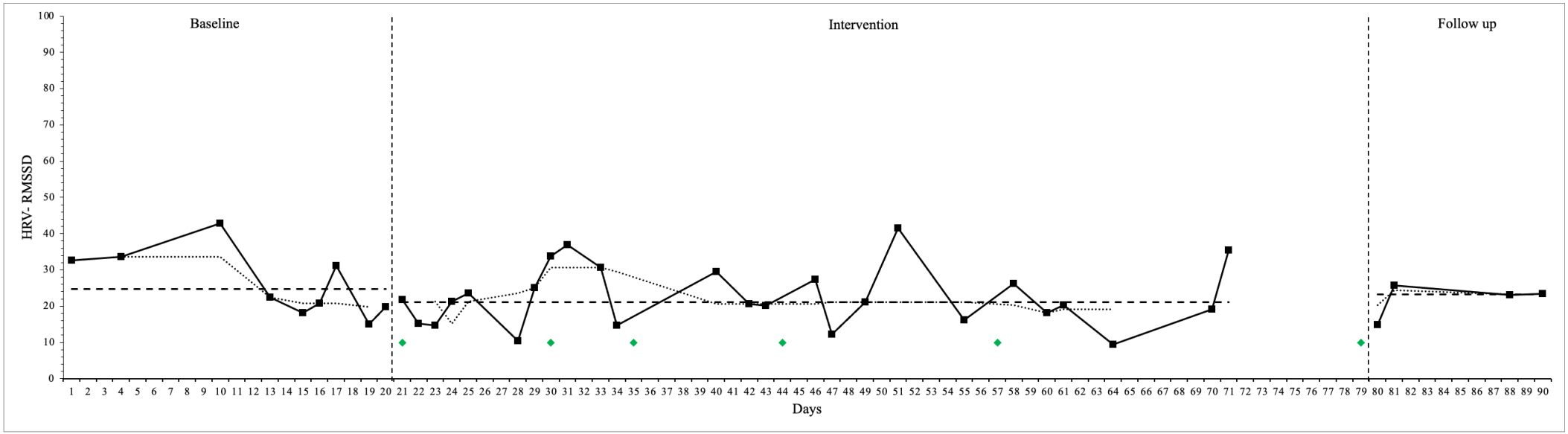


Figure 5.4

Participant B Raw Data for HRV - RMSSD



Participant C (PtC)

PtC scored 1 on the ACE questionnaire. She was randomised to a two-week baseline. She chose "Over the last 24 hours, how much have you snacked not due to hunger?" as her chosen behaviour.

PtC completed 13 days of baseline phase with 33 VAS data points across three questions (84.62% completion), 63 days of intervention phase, with 88 data points (46.56% completion rate) and 8 days of follow up, with 9 data points (37.5% completion rate).

PtC had struggled with depression for a number of years and presented with flattened affect and avolition. When we started our intervention, her daughters were undergoing support for their mental health which was understandably impacting the participants mood. In session four, she told me that she had doubled her dose of sertraline due to feeling helpless with her mood. She identified a certain 'closing of the therapy book' between sessions which meant she struggled to implement techniques into her daily life. We tried to rectify this by having self-initiated prompts and reminders from session four though the success of this was short lived.

In session five, her daughter's health worsened and due to this cancelled two sessions, meaning there was a long period of 25 days between session five and six. This participant most identified with the dorsal vagal state, retreating into immobilisation for protection from the perceived threats in her life. Implementing techniques and mobilising the body felt overwhelming and alongside the symptoms of depression made change difficult.

Visual and TAU-U Analysis

For body awareness, there is slight drop in central tendency between baseline and intervention. There is increased variability across baseline compared to intervention. This variability reduced throughout the invention, especially following session three and the introduction of the ANS tracker. However, this may be due to the increased amount of

missing data from session four which could overlook possible variability. There were no statistical differences between phases.

For emotion regulation, there is a slight increase in median between baseline and intervention. There is a period of increased scores throughout the first week of intervention, though in week four, from day 42, there is a slight downward and maintained trend in scores which coincides with increased difficult life events with the care of the participant's daughters and reported low mood. Although there is a marked downward trend in the follow up phases, conclusions cannot be drawn due to the lack of data. There were no statistical differences between phases.

For emotional eating, there appears to be a downward trend during baseline though Tau-U did not show any statistical trend in baseline. There is a drop in score for the final data point of baseline, and lower scores are maintained and continue to reduce following the introduction of the intervention. This is evident in trend, level and non-overlap analyses demonstrating a significant difference between baseline and intervention (Tau-U = -.73, $p < .001$). Although there is a gap in raw data and minimal data points for follow up, the downward trend continues with a reduction in level, and the combination of intervention and follow up compared to baseline is significant (Tau-U = -.73, $p < .001$). The lack of significant difference between intervention and follow up may be due to there being so few follow up data points ($n = 3$) and it would be interesting to see if the participant had continued completing measures whether this trend would have been further maintained or even continued to drop.

Overall, the low completion rates of measures reflects the level of engagement with the intervention. It is hypothesised that depression, the associated symptoms of avolition and the feeling of being overwhelmed when coming out of a protective dorsal vagal state acted as a barrier to engagement and outcomes. However, significant changes in chosen behaviour

suggest that alternative emotion regulation strategies were being employed or that at the least, emotional eating was being less frequently used and this change could tentatively be related to the intervention.

For HRV, 5/49 HRV data points were removed for poor quality which meant there was only one data point in follow up period. Therefore, this phase was not assessed in visual or Tau-U analysis. There is a reduction in variability evident towards the end of baseline, which increases as the intervention is introduced and again slightly decreases towards the end of the intervention. There were no statistical differences.

Figure 6.1

Participant C Raw VAS Data for Body Awareness

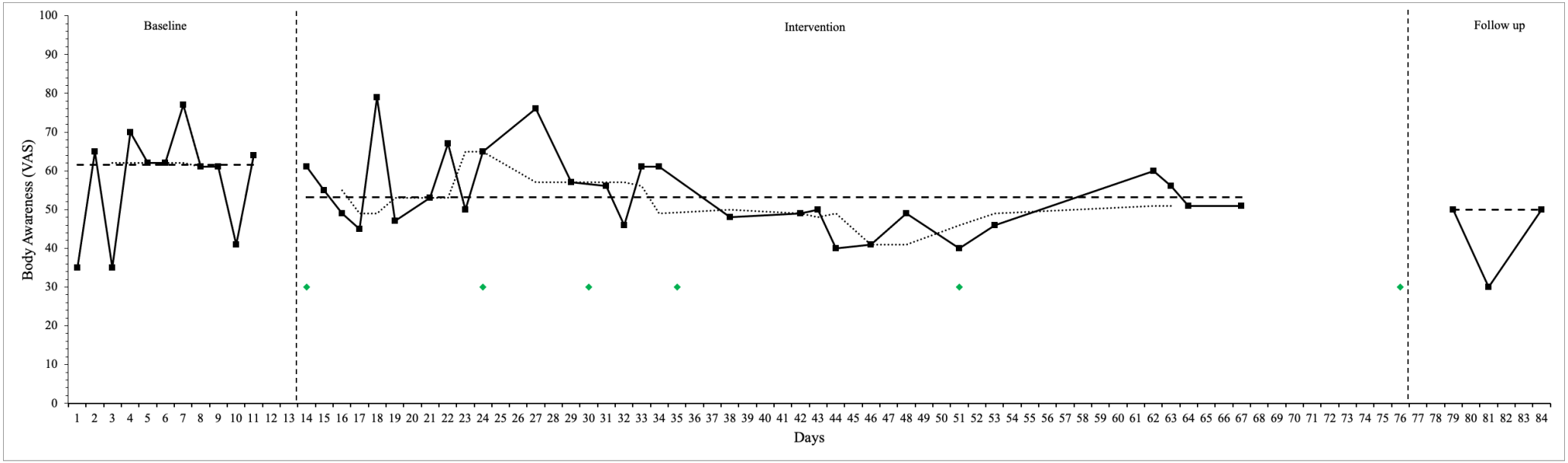


Figure 6.2

Participant C Raw VAS Data for Emotion Regulation

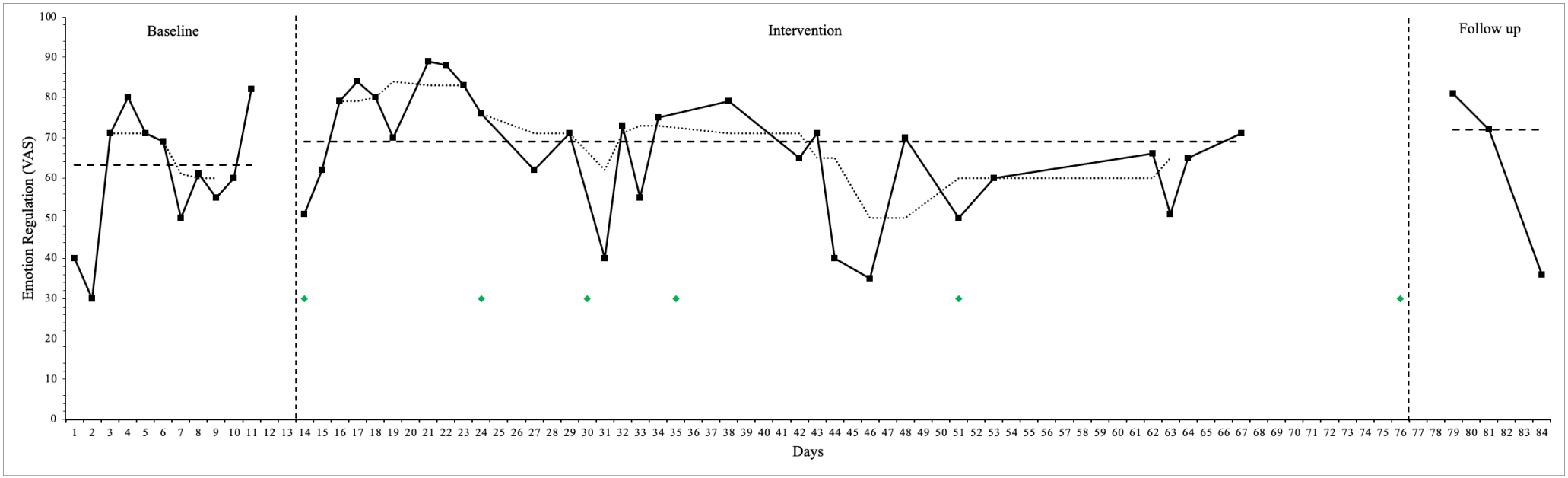


Figure 6.3

Participant C Raw VAS Data for Chosen Behaviour

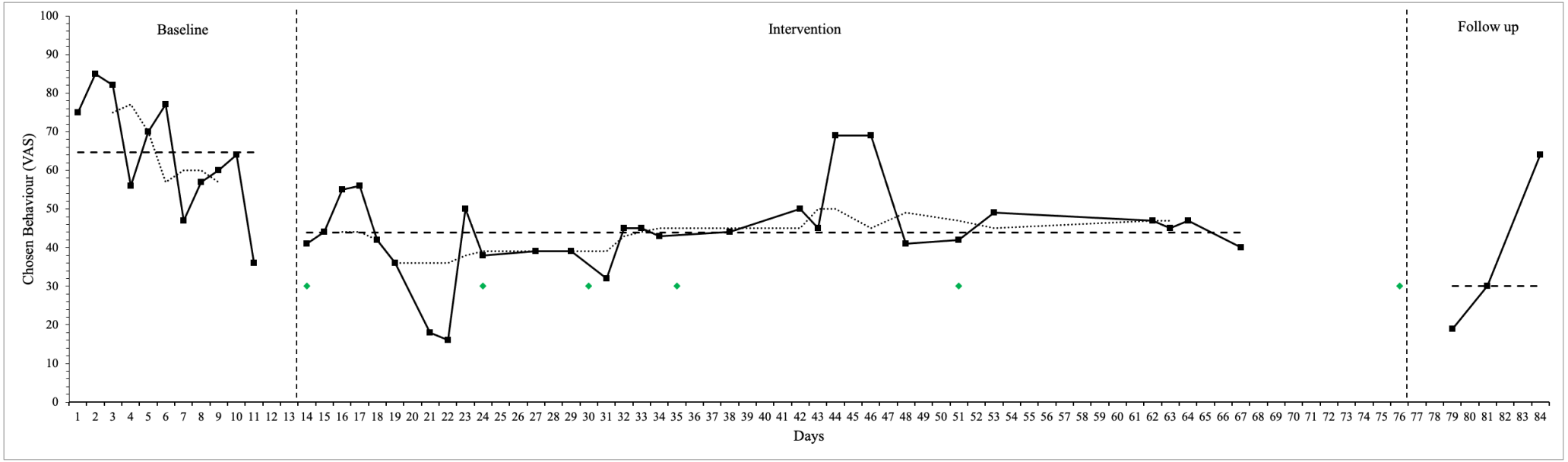
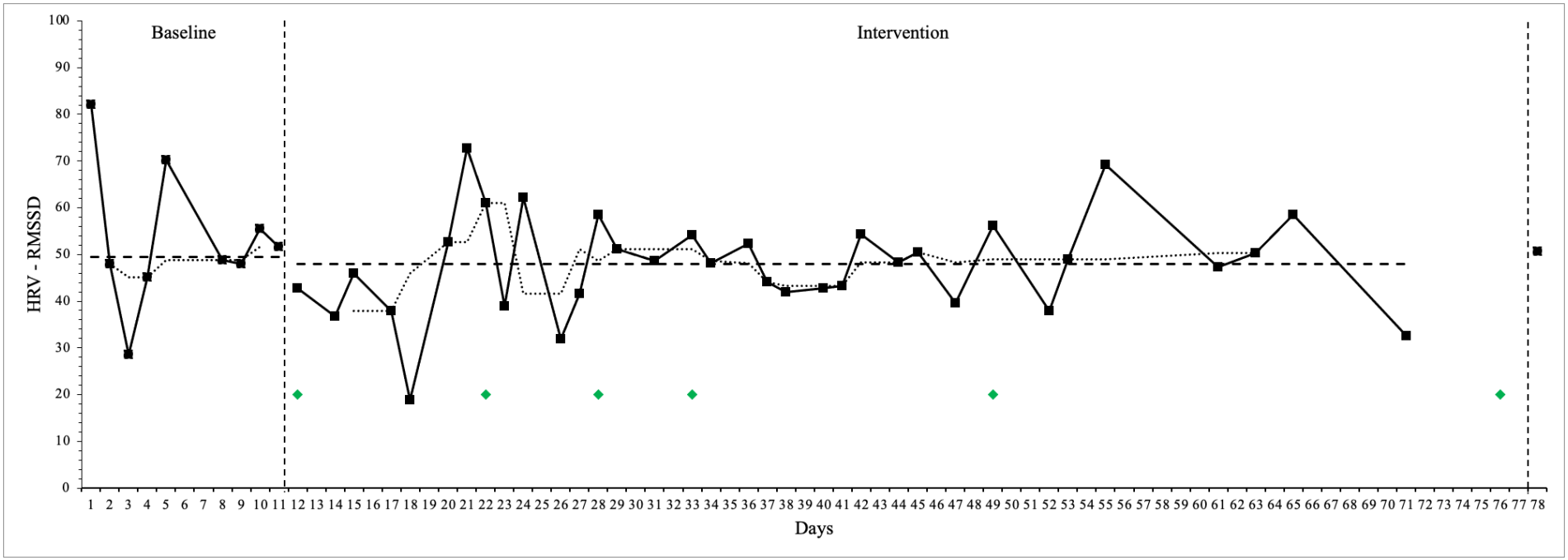


Figure 6.4

Participant C Raw Data for HRV - RMSSD



Participant D (PtD)

PtD scored 4 on the ACE questionnaire. She was randomised to a two-week baseline. Although this participant dropped out after session five of the intervention phase, as there was a minimum of five data points in this phase, in line with WWC standards (2017), the data can be used for analysis.

PtD completed 17 days of baseline phase with 48 VAS data points across three questions (94.12% completion), 62 days of intervention phase, with 159 data points (85.48% completion rate).

She chose "Over the last 24 hours, how much have you 'kicked off'?" as her target behaviour. She described this as raising her voice at others, losing control of what she's saying and feeling like she 'sees red'. Drop out occurred after a reported improvement in her psychological wellbeing and she moved back the final therapy session three times before she stopped responding to offered appointments. PtD described difficulties with emotion regulation and that she went from 0 to 100 very quickly which is reflected in her scores. She presented with an 'all or nothing thinking' style which again is reflected in her floor and ceiling responses. She lived with her partner, had a difficult relationship with her mother and her own four children had been taken into care. She oscillated between sympathetic activation and states of dorsal vagal dissociation that were highly sensitised to interactions with others.

Visual and TAU-U Analysis

Across VAS, PtD rated the ceiling value throughout the second week of baseline. This was explored with the participant during the first week of therapy and she clarified that these scores were a true representation rather than input error.

PtD explained that lower scores on body awareness represented increased attunement with her body. She described scores of 0 as reflecting a sense of peace with her body. When asked about the dramatic changes in scores, she described 'the change has happened by

tuning into body and knowing my own body'. For this participant, decreased body awareness scores represented a calmer felt sense of her body and improved body-self relationship.

Upward trends were evident across all VAS baselines, which were corrected for in statistical analyses. For body awareness, there is a clear reduction in level and a sharp downward trend following session three. This coincides with the introduction of ANS tracking, where she tracked 3-4 times per day and reported increased body attunement. This is supported by a significant difference between baseline and intervention phases (Tau-U = -.77, $p < .001$).

She explained that for emotion regulation, she had interpreted a high score as emotionally dysregulated. Therefore, for this participant, it is hypothesised that the emotion regulation score would decrease as a result of the intervention. Visual analysis demonstrates ceiling scores which are mostly maintained until session three when there is a pronounced drop which remains low with three marked spikes. The downward trend following session three coincides with the introduction of regulation strategies including walking to regulate sympathetic activation and baths to support ventral vagal. This is confirmed by statistical analysis demonstrating a significant reduction between phases (Tau-U = -.82, $p < .001$).

For her chosen behaviour, there is a clear downward trend from session three and then a plateau of minimal to zero occurrences of "kicking off", with three notable spikes which correspond with spikes for body awareness and emotion dysregulation. There was a significant difference between baseline and intervention for her chosen behaviour with a Tau-U very close to one (Tau-U = -.96, $p < .001$) which would reflect the extreme scoring.

Overall, PtD demonstrates significant changes across all three VAS in the direction that is positively meaningful for her. Extreme scoring is reflected in the Tau-U value and significance values and therefore should be interpreted with caution.

For HRV, 12/69 data points were removed for poor quality signal. There is a decrease in central tendency between baseline and intervention and a difference in phases was confirmed by statistical analysis (Tau-U = -.46, p = .02). This suggests HRV decreased as a result of the intervention, contrary to hypotheses.

Figure 7.1

Participant D Raw VAS Data for Body Awareness

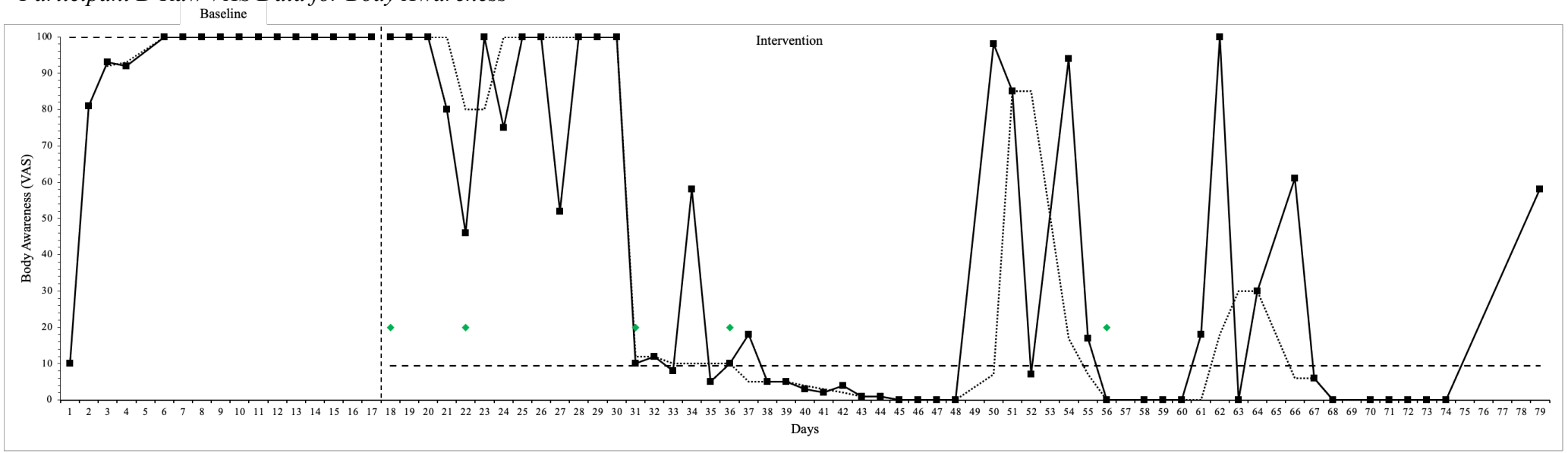


Figure 7.2

Participant D Raw VAS Data for Emotion Regulation

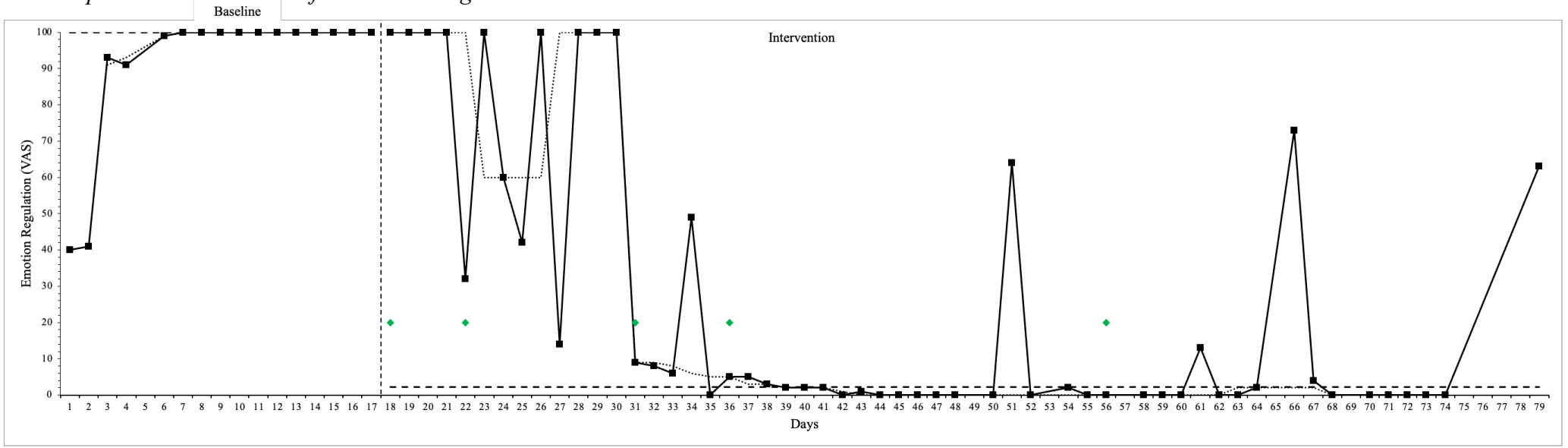


Figure 7.3

Participant D Raw VAS Data for Chosen Behaviour

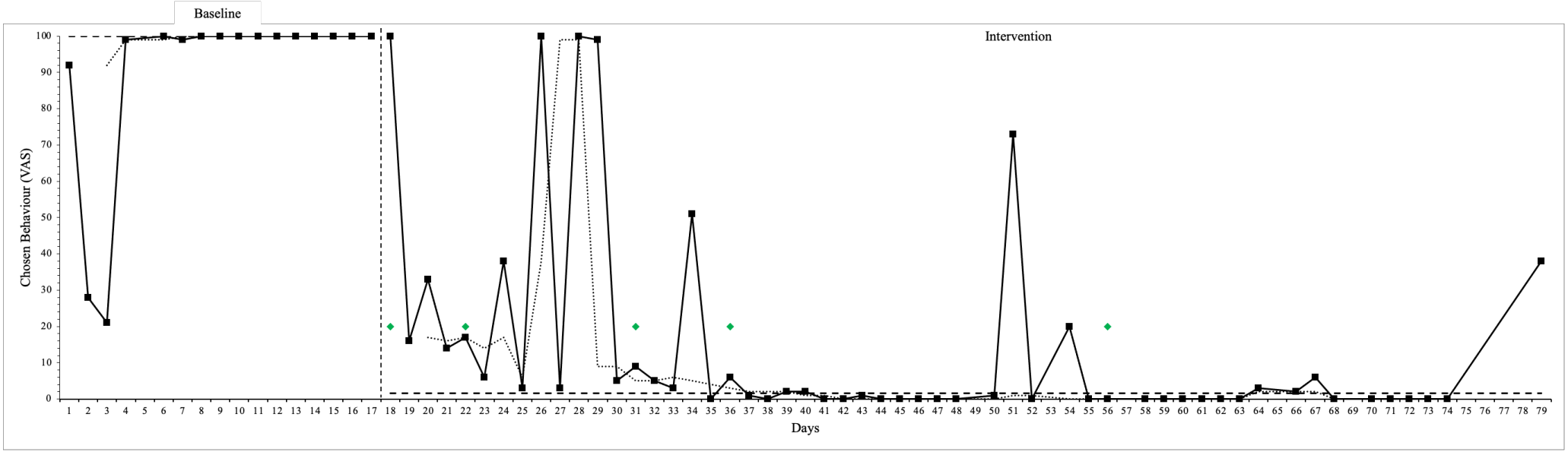
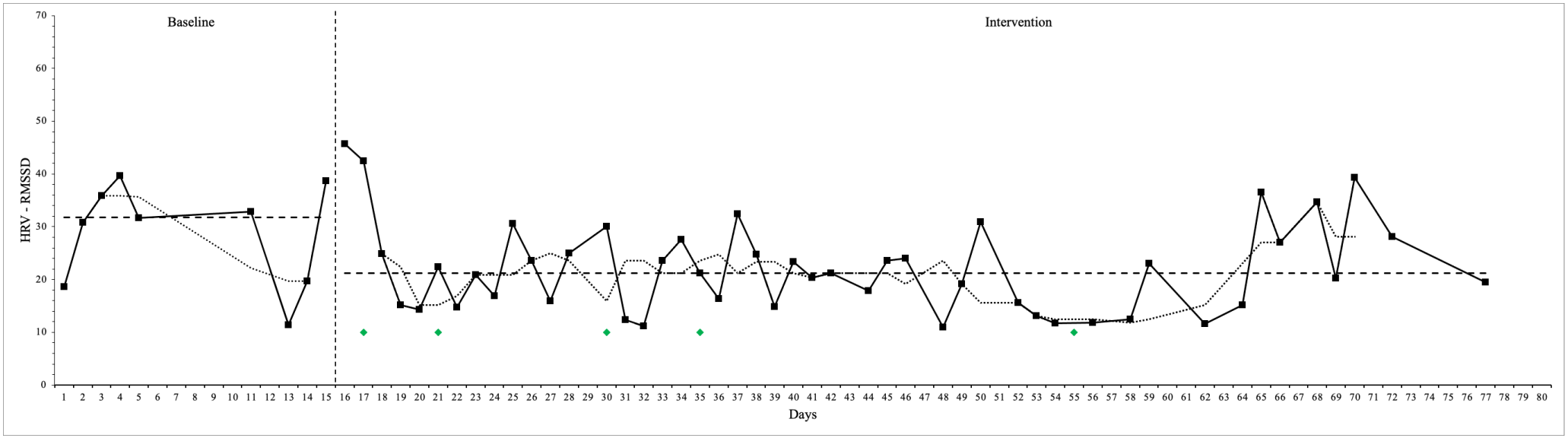


Figure 7.4

Participant D Raw Data for HRV - RMSSD



Participant E (PtE)

PtE scored 8 on the ACE questionnaire. She was randomised to one week baseline. She chose "Over the last 24 hours, how much have you over-eaten in order to prevent tiredness?" as her target behaviour.

PtE completed 7 days of baseline phase with 18 VAS data points across three questions (85.71% completion), 51 days of intervention phase, with 111 data points (72.55% completion rate) and 25 days of follow up, with 51 data points (68% completion rate).

She worked a demanding job that was heightened due to self-imposed high standards and difficulty in finding a work life balance. She told me that she would eat food to maintain energy levels and then crash, a cycle which was leading to a sense of burn out. She described high levels of sympathetic activation. In the introduction of strategies, an initial barrier was implementing these during work time, arguably when she needed it most. She was able to see the unworkability of these rules and noticed that when she was able to implement breathing during her workday it bought her a sense of clarity and increased productivity, breaking the cycle of pushing through. Given her preoccupation with work, she found it difficult to remember to implement strategies and a key change moment was the introduction of visual reminders following session four that supported integration into her life.

Visual and TAU-U Analysis

There is a downward trend during baseline for body awareness which was confirmed and corrected for in statistical analysis. There is a clear immediate increase in central tendency to body awareness following the introduction of the intervention. Scores interestingly trend downwards between session three and four before trending upwards to a position which is maintained, with reduced variability, from session four throughout follow up. Slight downward trends between session two and three could be explained by stress as her grandmother was having surgery. We spent some time thinking about this in session four and

implementing a plan to include visual reminders to check in with the body, which may explain the upward trend. There was a significant difference between baseline and intervention for body awareness (Tau-U = .95, $p < .001$), intervention and follow up (Tau-U = .74, $p < .001$) and an overall difference between baseline and the combination of intervention and follow up phases (Tau-U = .97, $p < .001$). This suggests a positive impact of the intervention on body awareness.

Emotion regulation showed little pattern across baseline. Central tendency increased with the introduction of the intervention. There was a significant difference between baseline and intervention for emotion regulation (Tau-U = .88, $p < .001$). There is a clear upward trend for emotion regulation following session four which coincides with the introduction of visual reminders. Scores remain high with reduced variability from session four. Interestingly there is a marked drop in level for follow up with immediate latency following withdrawal of the intervention. The change between phases is evidenced by a highly significant non-overlap analyses (Tau-U = -.90, $p < .001$). This suggests that treatment effects were not maintained following withdrawal of the intervention, in fact they appear to return to baseline level. This could reflect the participant not continuing with the strategies or suggest the intervention is too short to allow for independent implementation for this participant. Overall, there was a significant difference between baseline and the combination of intervention and follow up phases (Tau-U = .61, $p = .02$) but this must be treated with caution given the visual analyses findings.

There is a slight increase in level between baseline and intervention for her chosen behaviour, though this is not significant. For her chosen behaviour, there is a large variability in the data, especially during intervention, without many clear trends. There appears to be a slight reduction in variability from session four which is maintained throughout follow up. There were no statistically significant non-overlap analyses between phases.

Overall, there seems to be an effect of intervention for body awareness that was maintained through to follow up. Although there was an effect of improved emotion regulation, treatment gains were not maintained when treatment ceased. Across VAS, lower initial scores allow more scope for change for this participant. There were no changes to her chosen eating behaviour. Furthermore, there is a pattern of decreased variability in the second half of the intervention phase for all VAS. For this participant, this could reflect the introduction of visual reminders which supported implementation.

For HRV, 4/43 HRV data points were removed due to poor signal quality. There is a slight reduction in level from baseline to intervention, though this was not significantly different. However, there were periods, such as between days 25-48 where there was only one data point. The level of missing data in this period threatens the validity of conclusions that can be drawn from the data. HRV level again drops between intervention and follow up, a difference between phases which is confirmed by statistical analysis (Tau-U = -.41, $p = .04$). Overall HRV showed reductions, contrary to the hypothesised direction of change.

Figure 8.1

Participant E Raw VAS Data for Body Awareness

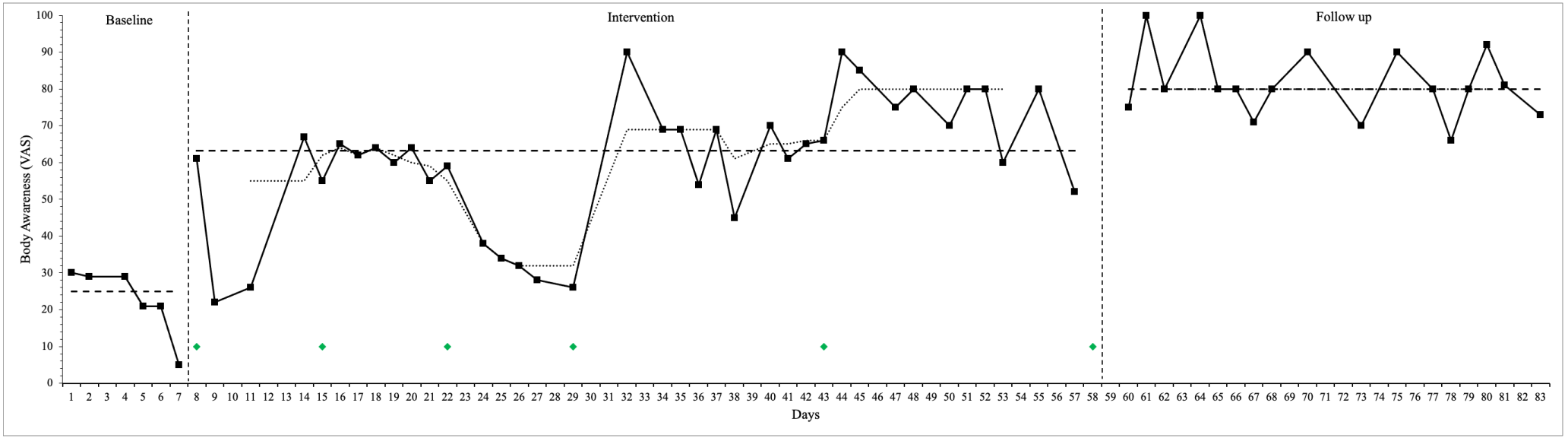


Figure 8.2

Participant E Raw VAS Data for Emotion Regulation

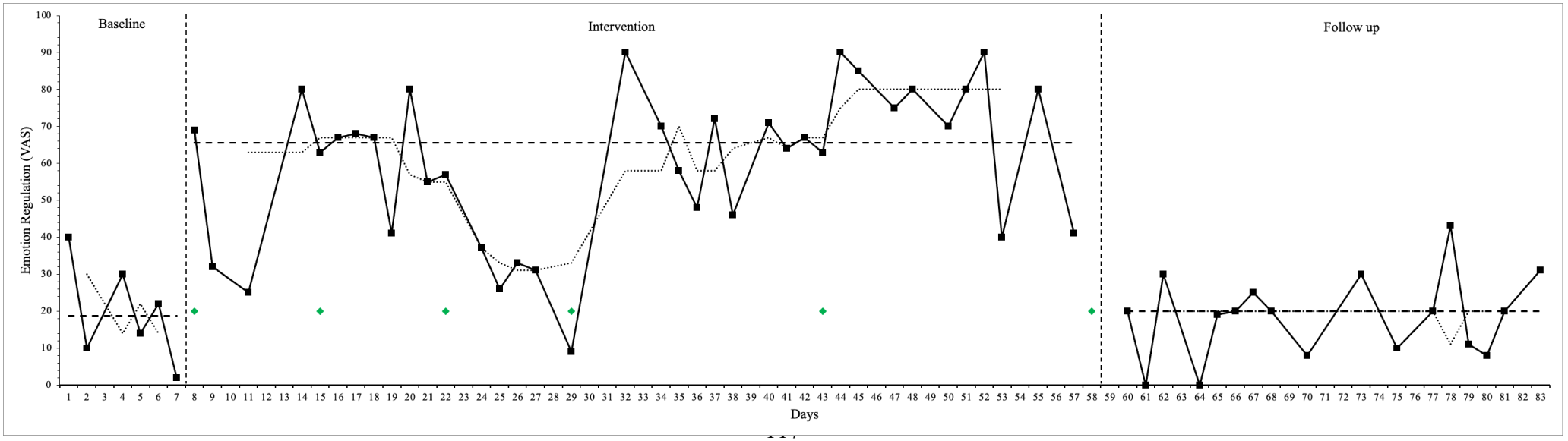


Figure 8.3

Participant E Raw VAS Data for Chosen Behaviour

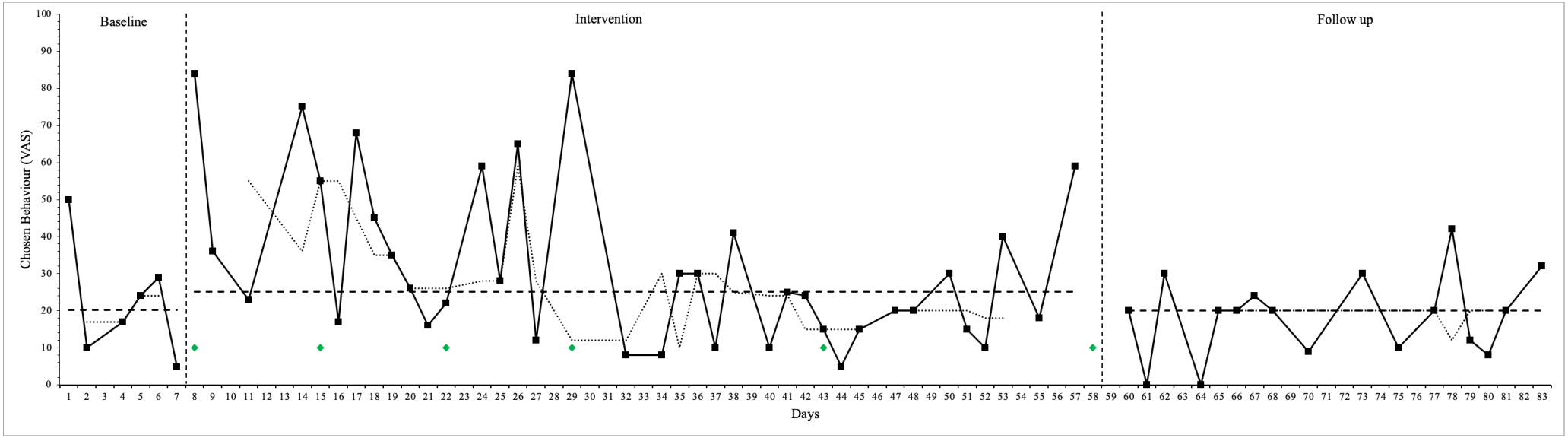
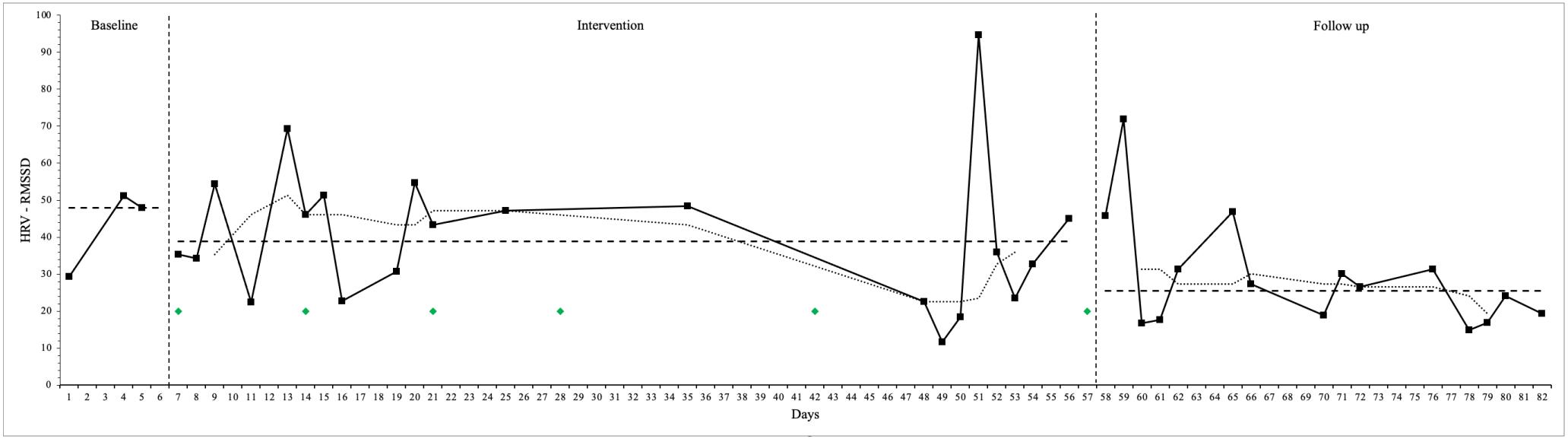


Figure 8.4

Participant E Raw Data for HRV - RMSSD



Participant F (PtF)

PtF scored three on the ACE questionnaire. She was randomised to one week baseline, though due to mutual availability, started intervention after 12 days of baseline. PtF completed 12 days of baseline phase with 33 VAS data points across three questions (91.67% completion), 52 days of intervention phase, with 132 data points (84.62% completion rate), 19 days of follow up, with 33 data points (57.89% completion rate).

She chose "Over the last 24 hours, how much have you binge eaten?" as her target behaviour. These episodes of overeating did not include loss of control and therefore were not part of a binge eating disorder but instead eating beyond feelings of fullness. PtF had recently moved into independent living with her partner and was revelling in having their own space. This was contributing to a reduced experience of dorsal vagal that was previously triggered by the environment of her in-laws. She showed high dedication to implementing techniques and tracking outside of sessions and a high willingness and motivation to change. She reported a heightened sense of body awareness generally which she attributed to a self-diagnosed neurodevelopmental associated sensory sensitivity. This high attunement to bodily signals meant that therapy work focused on recognising the 'early warning signs' of autonomic shifts to allow for rapid implementation of behavioural strategies to regulate.

Visual and TAU-U Analysis

Following a slight downward trend in baseline, there is an increase in the intervention phase central tendency related to body awareness. This is confirmed by statistical analysis which showed a significant difference in body awareness from baseline to intervention (Tau-U = .50, p = .01). There is most variability during baseline compared to a reduction in variability from session four of the intervention, which coincides with the change to fortnightly sessions and is sustained into follow up. Increase in level is maintained for follow

up suggesting treatment gains were maintained. Baseline compared to the combination of intervention and follow up was significant (Tau-U = .54, $p < .01$).

There is marked variability in baseline for emotion regulation with no clear trend. There is a slight increase in the expected direction for central tendency when the intervention commences and difference between baseline and intervention is confirmed by statistical analyses (Tau-U = .46, $p = .02$). There is an immediate reduction in emotion regulation following the final intervention session which could correspond with the participant reporting increased negative emotions associated with the ending of therapy. There is a slightly reduced level in follow up, though there were no significant differences between intervention and follow up. There was significant difference between baseline and combined intervention and follow up (Tau-U = .43, $p = .03$) suggesting an overall effect of intervention on emotion regulation.

For her chosen behaviour, there is a clear reduction in level between baseline and intervention though considerable variability in both phases means there was no significant difference in phases in non-overlap analyses. There is a slight upward trend following session four as the frequency of sessions decreased and this is accompanied by a slight reduction in variability and an upward trend. Level is maintained through follow up. There were no significant differences between phases for chosen behaviour.

Overall, data suggests there was an effect of treatment on body awareness and emotion regulation, gains which were maintained through to follow up. There were few notable changes to chosen behaviour and no statistical differences.

A total of 35/77 HRV data points were removed due to poor signal quality. An initial increase in HRV following the introduction of the intervention was followed by a downward trend and then a period of reduced variability for HRV following session three. Reduced variability and no change in level is sustained through to follow up, though the lack of raw

data makes it difficult to draw conclusions due to possible omitted variability. There were no statistically significant differences in phases.

Figure 9.1

Participant F Raw VAS Data for Body Awareness

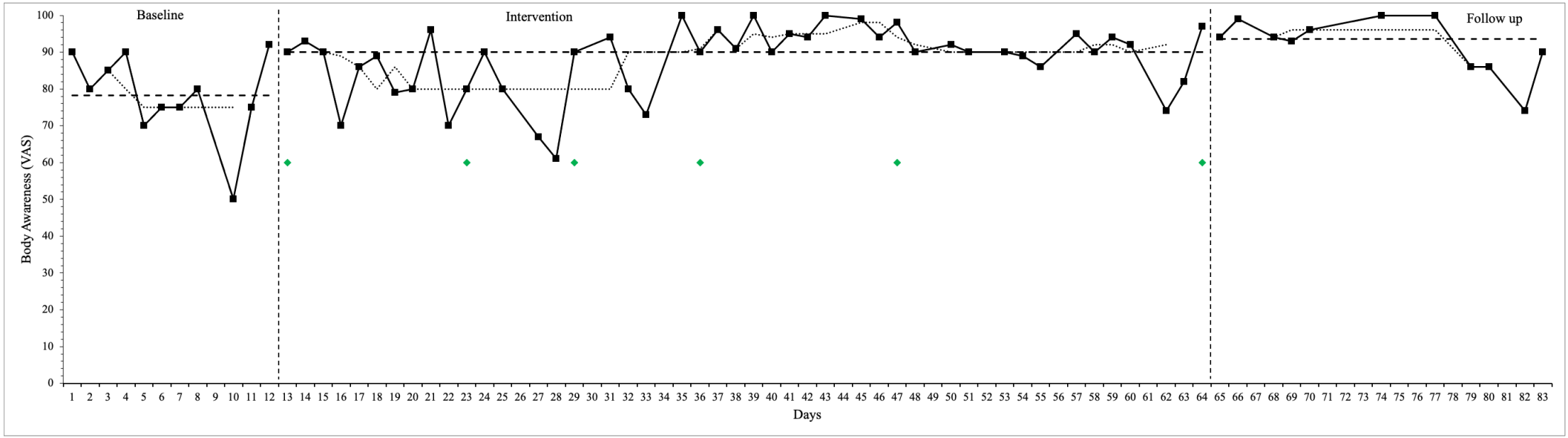


Figure 9.2

Participant F Raw VAS Data for Emotion Regulation

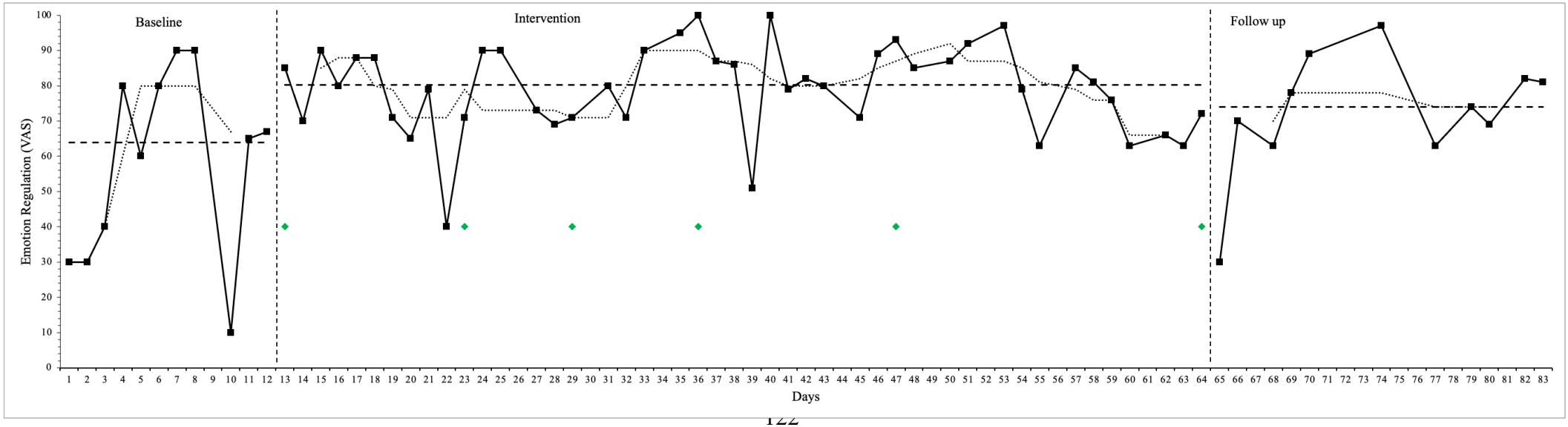


Figure 9.3

Participant F Raw VAS Data for Chosen Behaviour

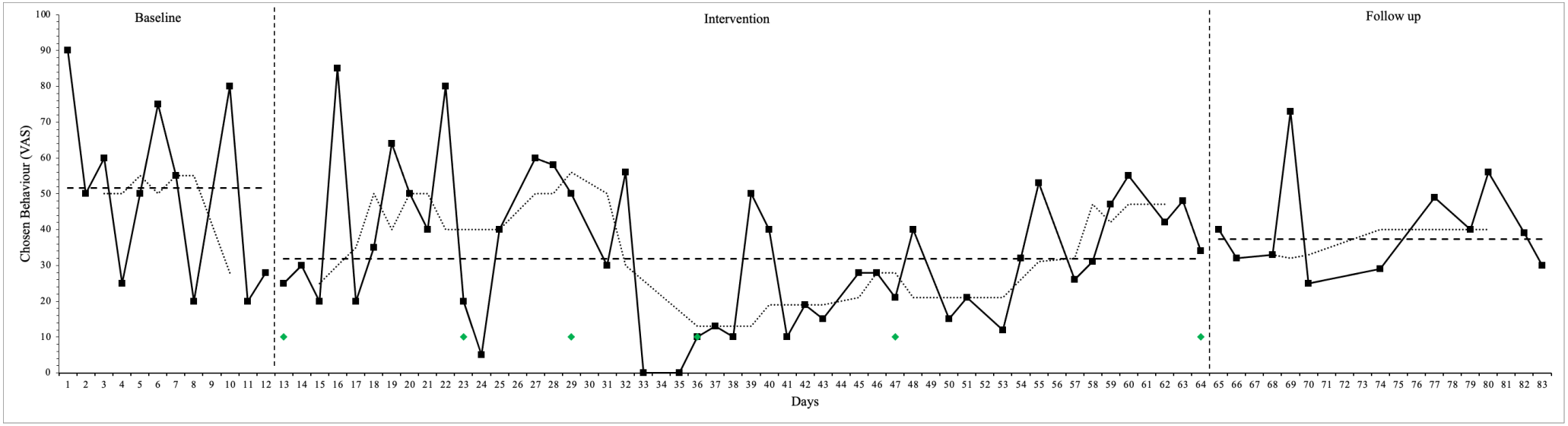
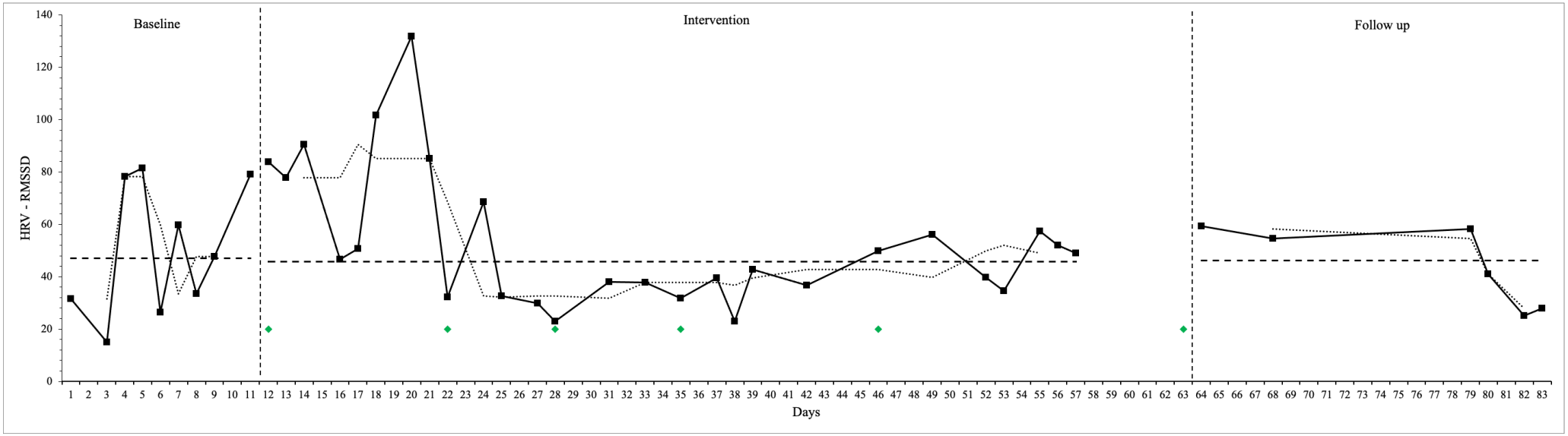


Figure 9.4

Participant F Raw Data for HRV - RMSSD



Participant G (PtG)

PtG scored 2 on the ACE questionnaire. She was randomised to one week baseline. PtG completed 7 days of baseline phase with 18 VAS data points across three questions (85.71% completion), 50 days of intervention phase, with 114 data points (76% completion rate) and 21 days of follow up, with 45 data points (71.43% completion rate).

She chose "Over the last 24 hours, how much have I unreasonably and uncontrollably reacted to *partner's* behaviour? as her target behaviour. Partner's name has been removed to protect their identity. She described this as saying hurtful words and raising her voice. PtG was a full-time carer for her partner and gave herself little permission to prioritise her own needs. Due to the stress of caring for her partner, sympathetic activation was driving her emotion regulation attempts. She felt overwhelmed with emotion and anger and found solace in the therapeutic relationship to express these feelings. She found bringing a PVT understanding to her bodily reactions validating and reassuring and it enabled her to bring some distance between herself and her body so that she could slow down the process of automatic behavioural reactions and make more conscious choices about how to emotionally regulate.

Visual and TAU-U Analysis

For body awareness, there was little variability in scores across all phases. There is little change from baseline to intervention in level and only a slight increase in level into follow up. There was a significant difference between intervention and follow up, demonstrating increased body awareness (Tau-U = .52, $p < .001$). Such changes can tentatively be attributed to the intervention.

Emotion regulation demonstrated more variability in scores with marked downward spikes. These correspond with ruptures in a friendship she reported between sessions. Level

remains consistent throughout phases. There were no significant differences in non-overlap between phases for emotion regulation.

From the introduction of the intervention, there is a clear downward trend for her chosen behaviour until session three. The downward trend, despite three spikes, continues to drop and then sustain a low level for follow up. There is a clear drop in level between baseline and intervention and this further drops in follow up phase. There was a significant difference between baseline and intervention (Tau-U = -.59, p = .02), intervention and follow up (Tau-U = -.51, p = .03) and the combination of intervention and follow up compared to baseline (Tau-U = -.65, p = .01).

Overall, there was little evidence of intervention effect on body awareness and emotion regulation. There was a change in follow up body awareness, but this cannot be attributed to the intervention with certainty. The data suggests a significant effect of intervention on chosen behaviour, with demonstrable significant changes from baseline to intervention and further gains in follow up.

For HRV data, 46/77 were excluded for poor signal quality. Visual inspection of central tendency, trend and variability of the data reveal little pattern which was confirmed by statistical analysis. Lack of findings may be due to the high number of excluded data.

Figure 10.1

Participant G Raw VAS Data for Body Awareness

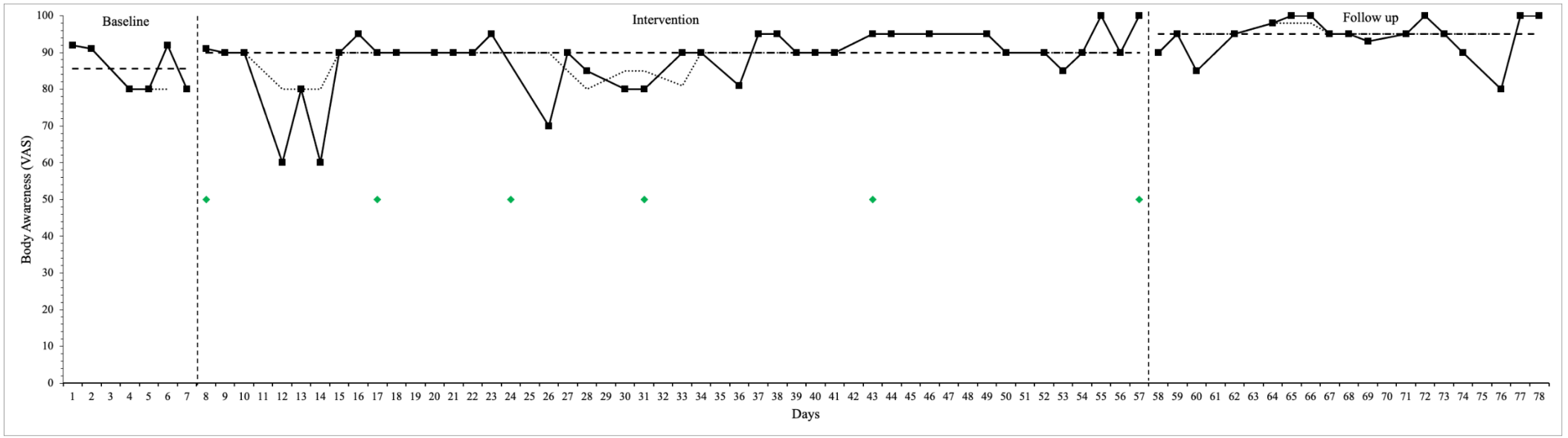


Figure 10.2

Participant G Raw VAS Data for Emotion Regulation

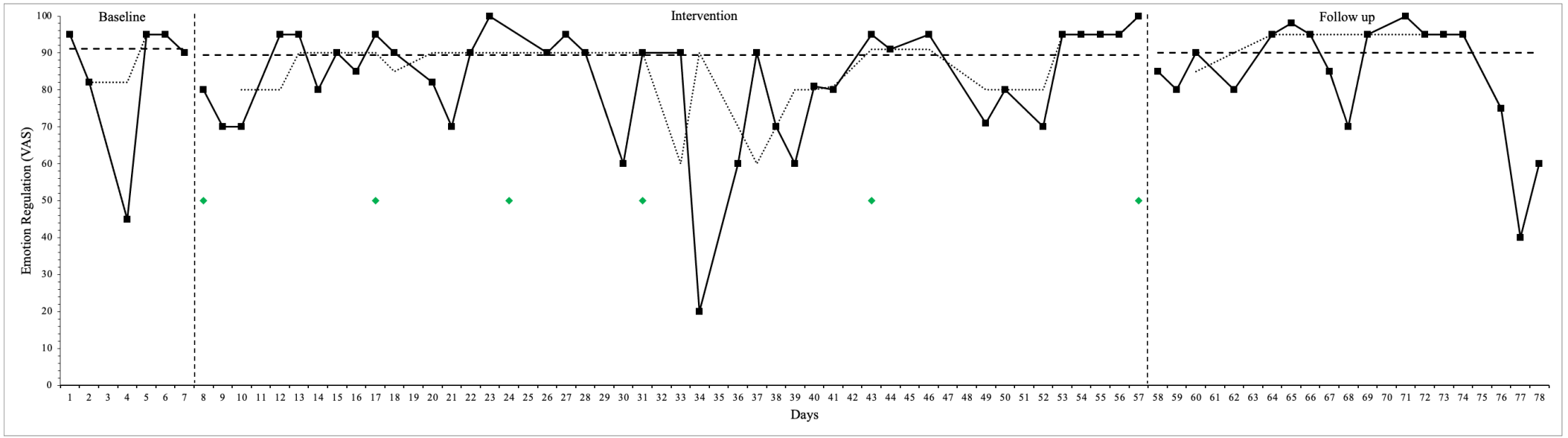


Figure 10.3

Participant G Raw VAS Data for Chosen Behaviour

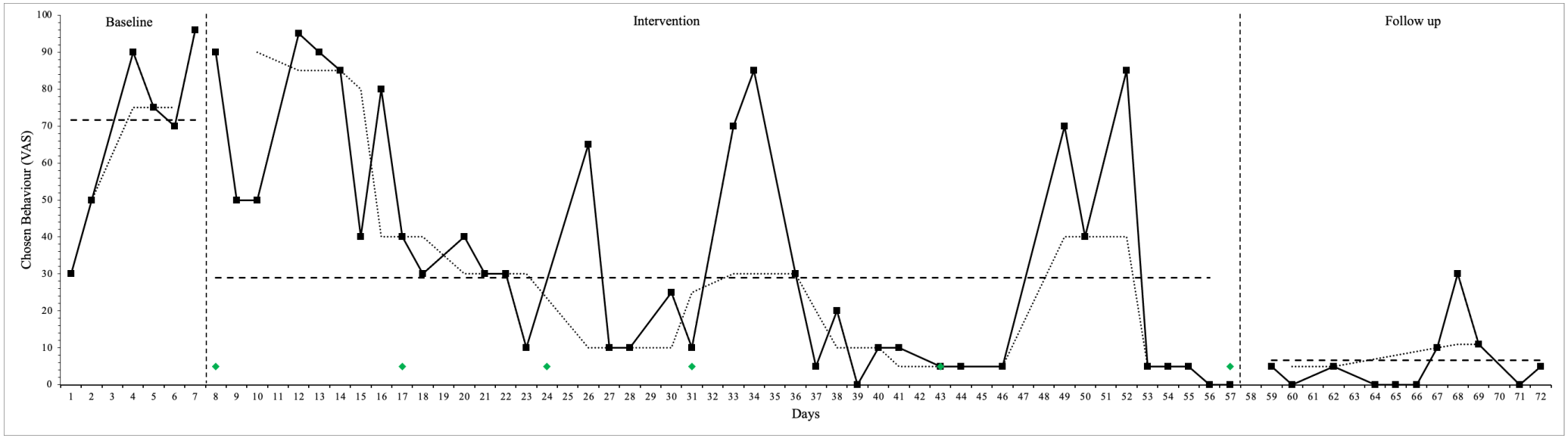
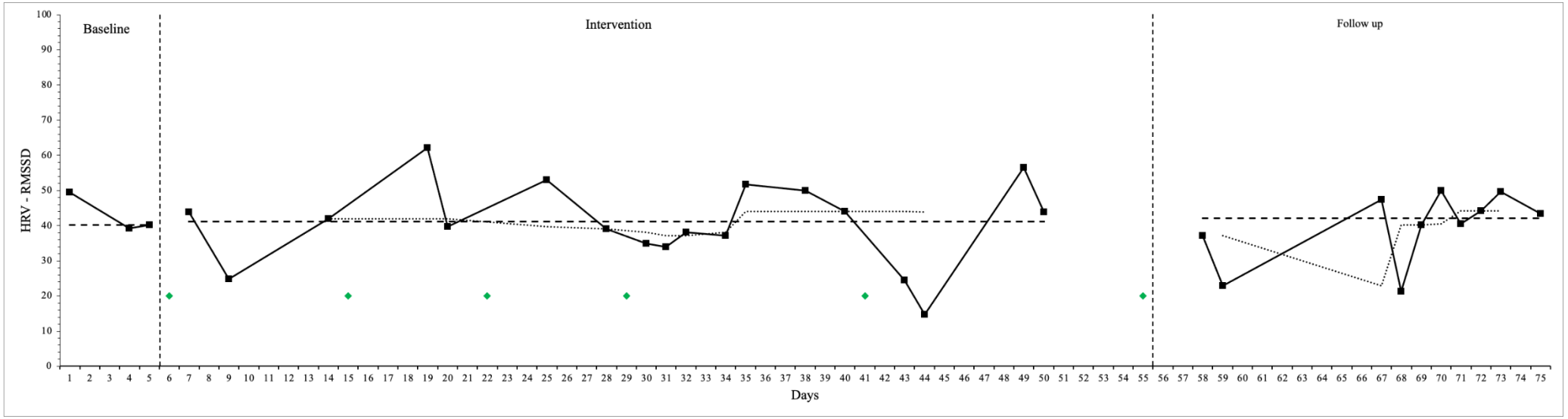


Figure 10.4

Participant G Raw Data for HRV - RMSSD



Participant H (PtH)

PtH scored three on the ACE questionnaire. She was randomised to a two-week baseline. PtH completed 13 days of baseline phase with 36 VAS data points across three questions (92.31% completion), 64 days of intervention phase, with 159 data points (82.81% completion rate) and 20 days of follow up, with 39 data points (65% completion rate).

She chose "Over the last 24 hours, how much have you turned to eating because of your emotions?" as her target behaviour. PtH worked as a tutor and reported taking on a lot of the stress of her students. She spent a lot of time and emotional energy organising care for her disabled daughter leading to chronic sympathetic activation and de-prioritisation of her own needs. She conflated stress with productivity and held worries about allowing herself to shift into ventral vagal for fear of being labelled lazy. Emotional eating, mainly high sugar high fat foods, served to maintain the 'hamster wheel' of sympathetic driven productivity, though this was inevitably followed by physical and emotional crashes. Opportunities for co-regulation had been neglected due to these crashes in energy and therapy supported recognition, from session five, of the power of social engagement to replenish energy stores and regulate.

Visual and TAU-U Analysis

For body awareness, there is marked variability throughout baseline which continues into the first portion of intervention. There is no change in level between baseline and intervention and high overlap. Variability appears to reduce from around session five and this reduced variability is maintained for the weeks between session five and six and throughout follow up phase. This coincides with the increased focus on co-regulation and increased social engagement. There was a significant difference between intervention and follow up (Tau-U = .39, p = .03). As changes in variability occur before the withdrawal of intervention, this significant difference could tentatively be attributed to the intervention as a reflection of consolidation of techniques and slow latency of change.

For emotion regulation, there is little change in level or variability across phases. Variability remains high throughout all phases. There appears to be no effect of intervention on emotion regulation and no statistically significant results.

For her chosen behaviour, there is a slight increase in central tendency. There is an upward trend following session two, which coincides with the introduction of the ANS tracker and may reflect increased awareness of frequency of emotional eating due to active tracking multiple times a day. Variability slightly reduces from session five and the final portion of the intervention. There was a slight drop in central tendency from intervention to follow up and non-overlap difference was confirmed by statistical analyses (Tau-U = -.39, p = .03).

Overall, there was a pattern of reduced variability for body awareness and emotional eating in the final section of the intervention phase which was maintained through follow up. Confirmed by statistical analysis, this could suggest an effect of intervention that became apparent in the final stages. There was no effect of intervention on emotion regulation.

For HRV, 75/86 data points were removed due to poor quality. 3/86 were removed as they contained a value of zero. This left eight data points, zero for baseline, five for intervention and three for follow up phase. As there is no baseline data, this cannot be subjected to visual analysis as there is no comparison phase and therefore no conclusions about the effect of intervention on HRV for this participant could be drawn.

Figure 11.1

Participant H Raw VAS Data for Body Awareness

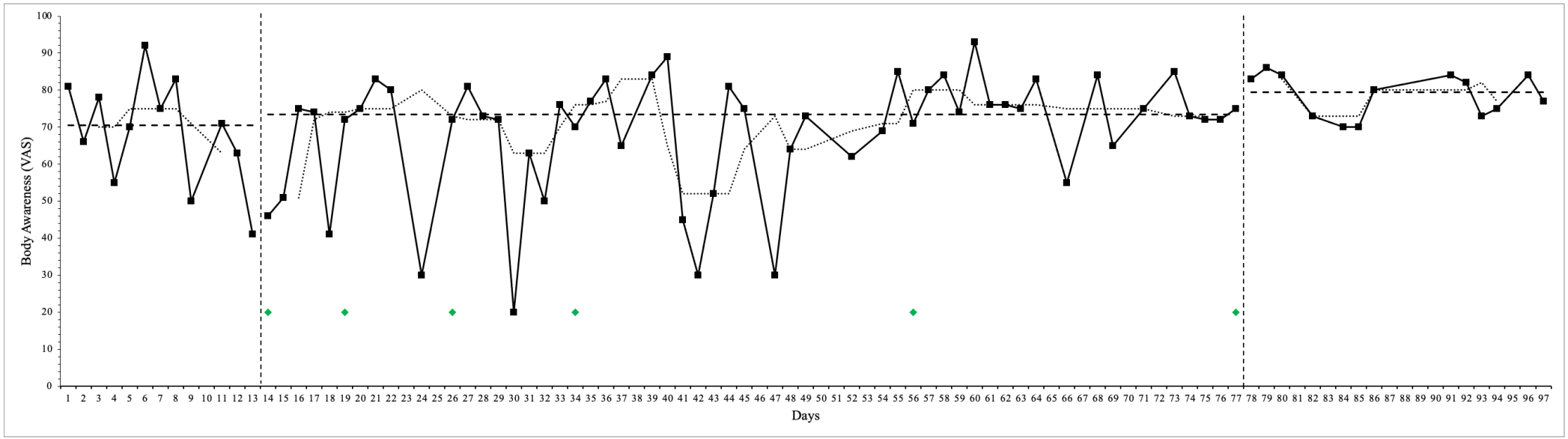


Figure 11.2

Participant H Raw VAS Data for Emotion Regulation

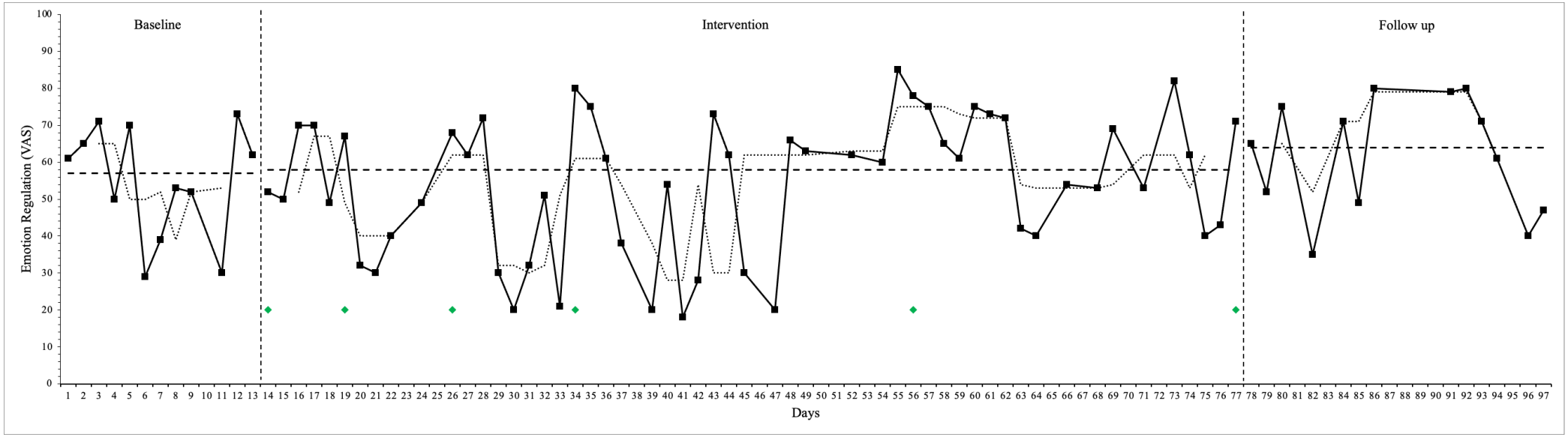
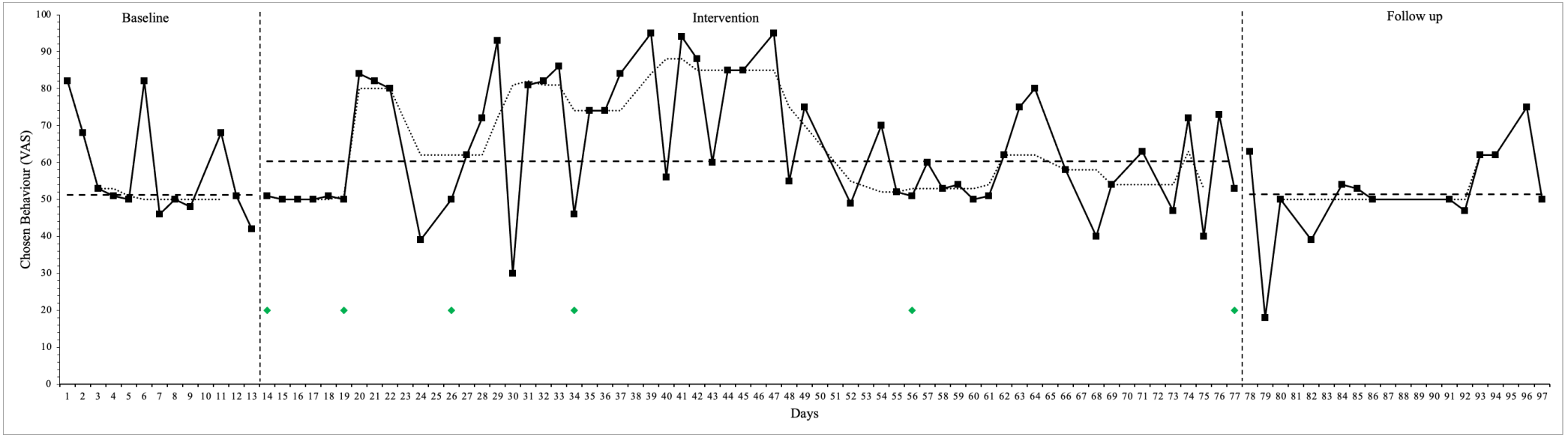


Figure 11.3

Participant H Raw VAS Data for Chosen Behaviour



Participant I (PtI)

PtI scored one on the ACE questionnaire. She was randomised to a three-week baseline. PtI completed 22 days of baseline phase with 60 VAS data points across three questions (90.91% completion), 50 days of intervention phase, with 146 data points (97.33% completion rate) and 21 days of follow up, with 60 data points (95.24% completion rate). She chose "Over the last 24 hours, how much have I eaten in response to my feelings?" as her target behaviour.

PtI had undergone bariatric surgery two and half years ago and had recently been supported with an intuitive eating intervention by the service, though had found her difficulties with tuning into her bodily signals a barrier to further progress with this. In PVTT she found it difficult to sit with uncomfortable emotional states and would cognitively seek the trigger which impeded her ability to implement behavioural strategies to regulate. She noticed that a level of disconnect from her body meant she did not have to face difficult emotions and that avoidance generally had become a natural coping mechanism. Eating served as an avoidance strategy and sometimes was followed by purging which further served to disconnect from emotional experience. Through body scans and gentle body-based enquiry in PVTT alongside the ANS tracker, she was able to bring awareness to bodily signals such as temperature changes, and muscle tension that supported increased body awareness, validation and thus permission to regulate in more helpful ways.

Visual and TAU-U Analysis

For body awareness, there was an upward trend and overall increase in level following introduction of the intervention. Change in phase is confirmed by statistical analysis, (Tau-U = .57, $p < .001$). Trend remains fairly in line with the central tendency, retaining a high level throughout intervention. There is an initial downward trend in follow up though this returns to meet the central tendency and a comparable level to intervention.

The combination of intervention and follow up compared to baseline was significant (Tau-U = .53, $p < .001$) suggesting an overall effect of intervention on body awareness.

For emotion regulation, there is relative stability in the baseline, confirmed by no statistical trends. There is a slight increase in level between baseline and intervention and difference in phase was confirmed by non-overlap analyses (Tau-U = .42, $p = .01$). There is a slight downward trend at the start of follow up which coincides with reduced body awareness. The combination of intervention and follow up compared to baseline was significant (Tau-U = .38, $p = .01$) which suggests an effect of intervention on emotion regulation which was maintained for follow up.

For her chosen behaviour, there is more variability compared to other VAS and a slight decrease in level between baseline and intervention. There was a significant difference between baseline and intervention (Tau-U = -.34, $p = .03$), evidencing a reduction. There is a slight upward trend in emotional eating following withdrawal of the intervention which corresponds to a decrease in body awareness and emotion regulation. There were no differences in non-overlap analyses.

Overall, analysis suggests a significant effect of intervention on increasing body awareness, emotion regulation and reducing emotional eating in line with hypotheses. These treatment gains were maintained through to follow up.

For HRV, there were 91 data points across all phases. No data was removed for poor quality. Despite this being the most intact data set, visual inspection of central tendency, trend and variability of the data reveal little pattern which was confirmed by statistical analysis.

Figure 12.1

Participant I Raw VAS Data for Body Awareness

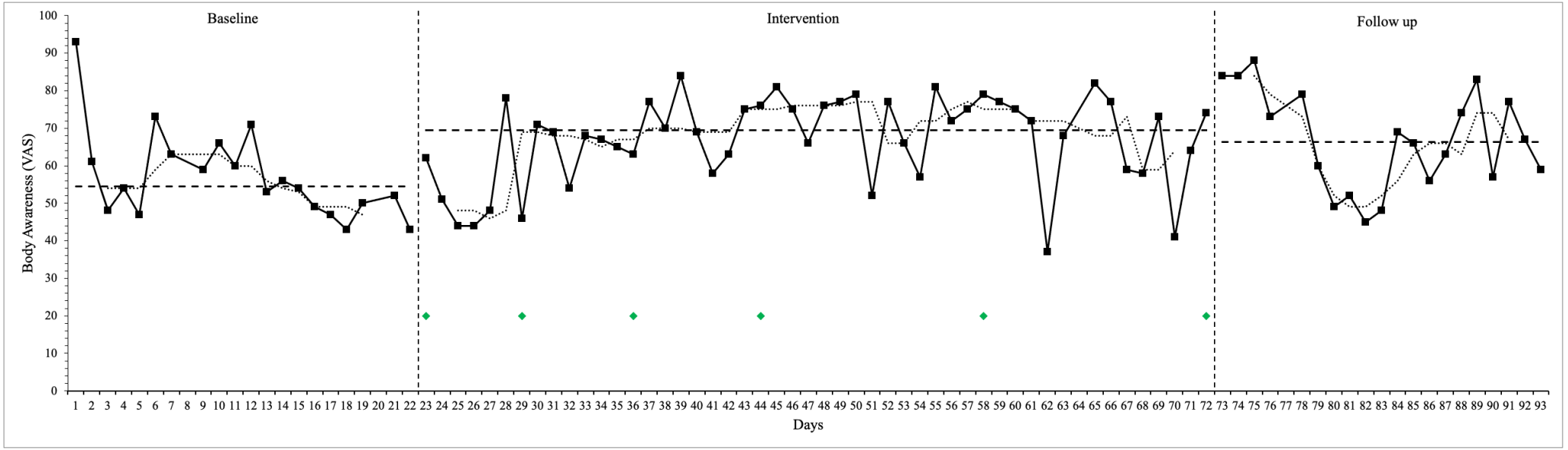


Figure 12.2

Participant I Raw VAS Data for Emotion Regulation

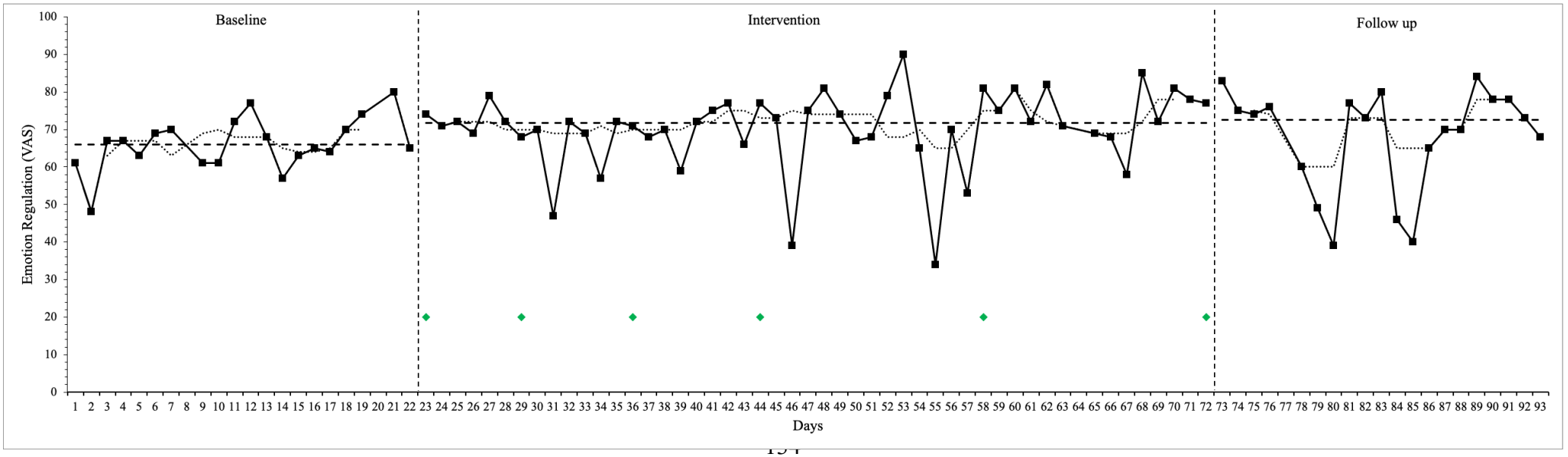


Figure 12.3

Participant I Raw VAS Data for Chosen Behaviour

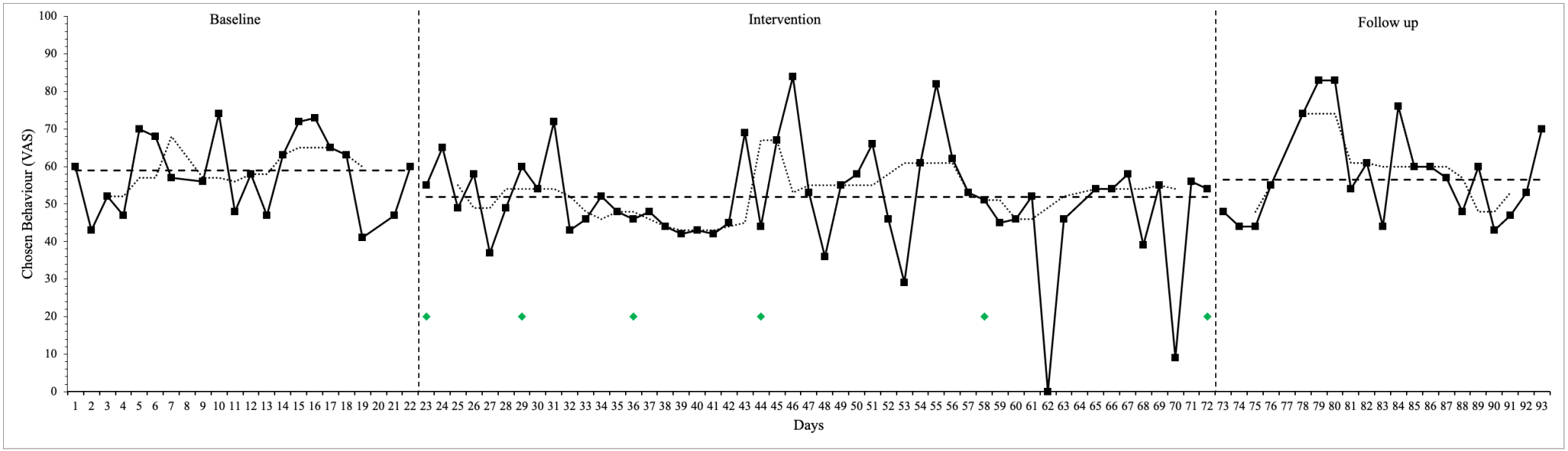
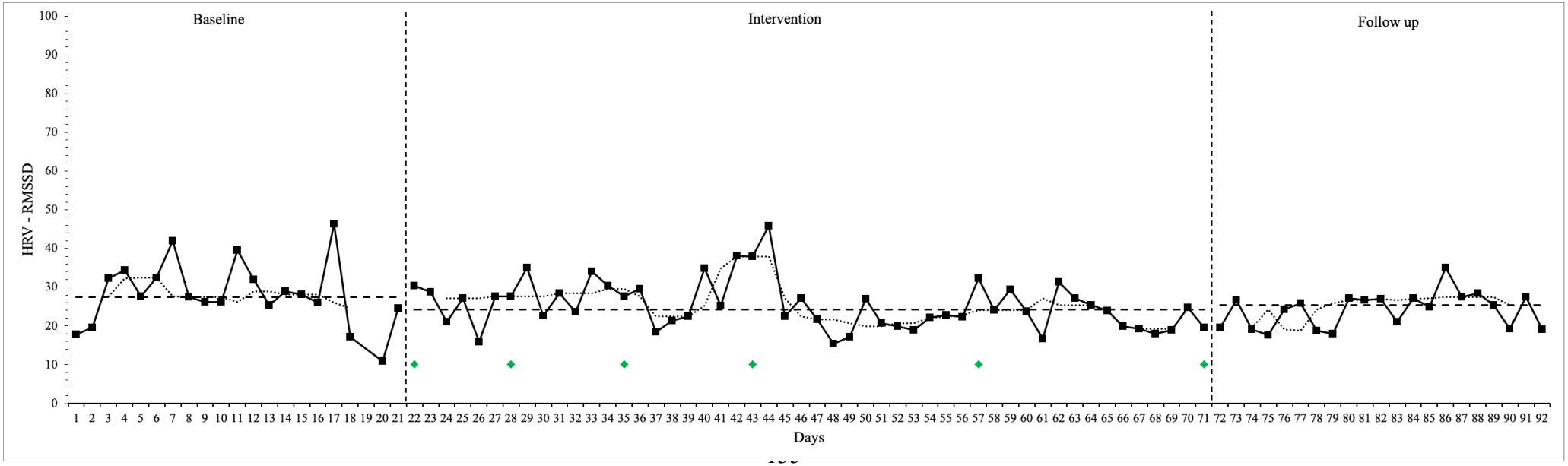


Figure 12.4

Participant I Raw Data for HRV - RMSSD



Omnibus Tau-U Effect Sizes

Across all participants, comparing baseline to the combination of intervention and follow up found significant improvements for body awareness (Tau-U = .27, $p < .001$), emotion regulation (Tau-U = .19, $p = .01$) and chosen behaviour (Tau-U = -.27, $p < .001$). A significant reduction in HRV comparing baseline to intervention phase was found (Tau-U = -.19, $p = .04$). It is important to note that causal inferences regarding the intervention cannot be inferred from significant weighted averages, especially given the concurrent nature of the design and the possible influence of external events (Parker & Vannest, 2012). All Tau-U data can be found in Appendix R.

Summary of SCED Data

Body Awareness

For body awareness, four participants, across three baseline lengths (PtD, PtE, PtF, PtI) demonstrated significant change (increase) from baseline to intervention. One of these participants did not complete follow up (PtD). Two participants, across two baseline lengths (PtF, PtI) sustained changes made in intervention throughout follow up. Five participants, across all three baseline lengths (PtA, PtB, PtE, PtG, PtH) demonstrated further significant change from intervention to follow up. One participant (PtC) showed no changes.

Emotion Regulation

For emotion regulation, five participants across three baseline lengths (PtA, PtD, PtE, PtF, PtI) demonstrated significant change from baseline to intervention. One of these participants did not complete follow up (PtD). Three of these participants, over two baseline lengths, either sustained (PtF, PtI) or continued to show significant improvements (PtA) from intervention to follow up. Conversely, one of these participants (PtE) showed a significant decrease in follow up, returning to baseline level.

One participant (PtB) showed a significant reduction in emotion regulation from baseline to intervention which significantly increased to follow up. Overall, there was a significant difference (reduction) in combination of intervention and follow up compared to baseline. Two participants (PtC, PtG) showed no changes in relation to emotion regulation.

Chosen Behaviour

For chosen behaviours, five participants across three baseline lengths (PtA, PtC, PtD, PtG, PtI) demonstrated significant reductions from baseline to intervention. One of these participants did not complete follow up (PtD). Four of these participants, over three baseline lengths, either maintained treatment gains (PtC, PtI) or continued to significantly reduce (PtA, PtG). One participant (PtH) demonstrated a significant reduction in chosen behaviour from intervention to follow up.

One participant (PtB) showed a significant increase in chosen behaviour during intervention compared to baseline. Two participants (PtE, PtF) showed no significant changes to their chosen behaviour.

Overall, this suggests an effect of intervention across at least three different participants, across three different baseline lengths for body awareness, emotion regulation and chosen behaviour. Treatment gains were sustained or continued to improve for three participants over two baseline lengths for body awareness, for three participants over two baseline lengths for emotion regulation and for four participants over three baseline lengths for chosen behaviour.

HRV

The majority of participants (PtA, PtB, PtC, PtF, PtG, PtI) showed no significant changes in relation to HRV across phases. Two participants (PtD, PtE) showed a significant reduction in HRV, contrary to the hypothesised directions. One participant (PtD) showed a

significant decrease between baseline and intervention and the other (PtE) showed a significant decrease between intervention and follow up.

Standardised Measures

Standardised measures assessed interoception (MAIA-2 and FFMQ-15) and emotion dysregulation (DERS). It was hypothesised that the intervention would lead to higher reported interoception and lower emotion dysregulation. The Leeds Reliable Change indicator was used to graph data of RC and CSC (Morley & Dowzer, 2014). All CSC calculations were assessed using Criterion B. The scatter plots below show pre-treatment scores which are an average of baseline scores compared to post-treatment scores and final data point to reflect follow up. Summaries of raw scores for standardised measures can be found in Appendix S.

Interoception (MAIA-2)

Across the eight items of interoception as measured by the MAIA-2, RC and CSC was assessed at post-intervention and at the final data point of follow up. A summary of the statistical change for each item of the MAIA-2 is presented in Table 4. Scatter plots are presented in Figure 13. Further to the results presented in Table 4, two participants (PtG, PtI) showed RC during follow up but not at the final data point for not-worrying. For attention regulation, three participants (PtA, PtG, PtH) showed RC during follow up but not at the final data point. For self-regulation, PtA demonstrated RC during follow up but not at the final data point. For body listening PtG showed RC during follow up but not at the final data point. For trusting, PtG showed RC during follow up but not at the final data point. A summary of raw scores and RC can be found in Appendix S.

Most participants showed RC on attention regulation (n=5), body listening (n=5) and trusting (n=5) and participant E showed the most occurrences of RC across seven items. Two

participants did not demonstrate change on any items (PtB, PtC). No participants demonstrated CSC.

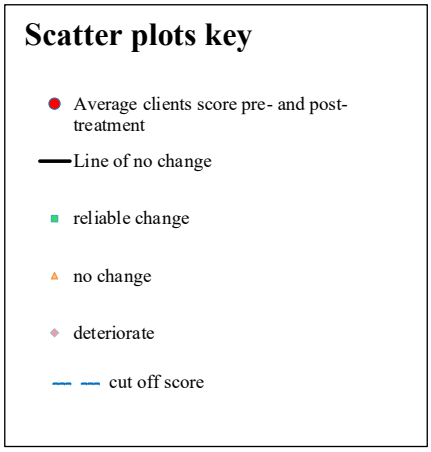


Table 4

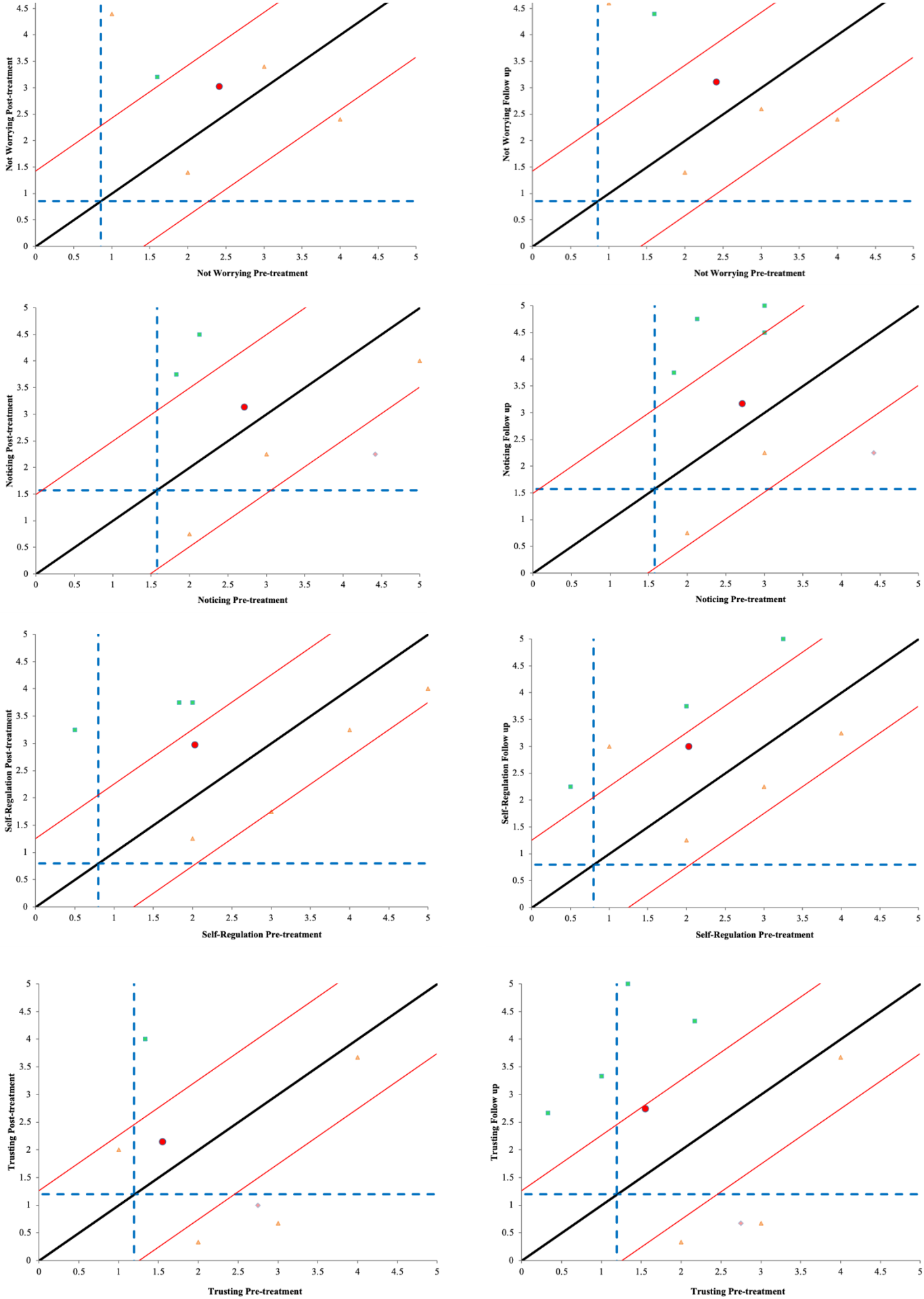
Summary of Statistical Change on MAIA-2

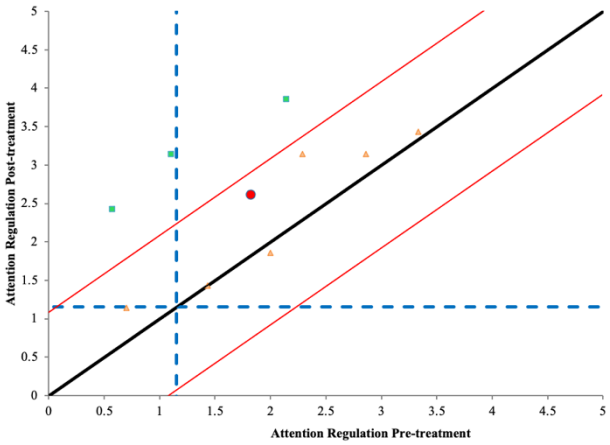
MAIA-2 Item	Pre-post intervention			Pre-final data point		
	Significant change	No significant change	Significant deterioration	Significant change	No significant change	Significant deterioration
Noticing	2 (PtA, PtH)	6 (PtB, PtC, PtE, PtF, PtG, PtH, PtI)	1 (PtD)	4 (PtA, PtE, PtG, PtH)	4 (PtB, PtC, PtF, PtI)	0
Not-Distracting	1 (PtE)	8 (PtA, PtB, PtC,PtD, PtF, PtG, PtH, PtI)	0	1 (PtE)	7 (PtA, PtB, PtC, PtF, PtG, PtH, PtI)	0
Not-Worrying	1 (PtE)	8 (PtA, PtB, PtC,PtD, PtF, PtG, PtH, PtI)	0	1 (PtE)	7 (PtA, PtB, PtC, PtF, PtG, PtH, PtI)	0
Attention Regulation	3 (PtA, PtE, PtI)	6 (PtB, PtC, PtD, PtF, PtG, PtH)	0	2 (PtE, PtI)	6 (PtA, PtB, PtC, PtF, PtG, PtH)	0
Emotional Awareness	1 (PtA)	8 (PtB, PtC,PtD, PtE, PtF, PtG, PtH, PtI)	0	1 (PtA)	7 (PtB, PtC, PtE, PtF, PtG, PtH, PtI)	0
Self-Regulation	3 (PtA, PtH, PtI)	6 (PtB, PtC, PtD, PtE, PtF, PtG)	0	3 (PtE, PtH, PtI)	5 (PtA, PtB, PtC, PtF, PtG)	0
Body Listening	3 (PtA, PtE, PtH)	6 (PtB, PtC, PtD, PtF, PtG, PtI)	0	4 (PtA, PtE, PtH, PtI)	4 (PtB, PtC, PtF, PtG)	0
Trusting	1 (PtE)	7 (PtA, PtB, PtC,PtD, PtF, PtG, PtH)	1 (PtI)	4 (PtA, PtE, PtF, PtH)	4 (PtB, PtC, PtG)	1 (PtI)

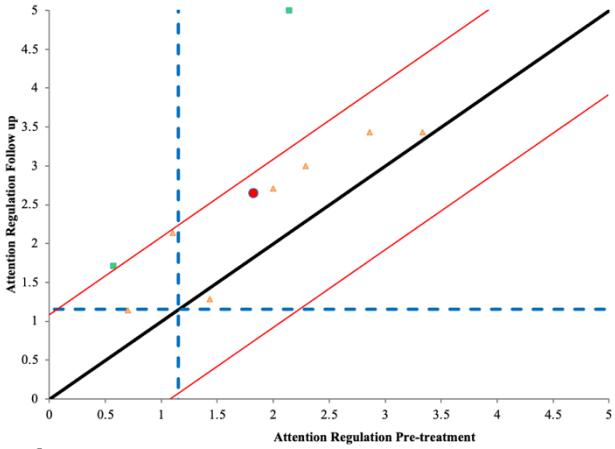
Note. MAIA-2 = multidimensional assessment of interoceptive awareness 2; Pre = average of baseline scores; Pt = participant. Significant change refers to reliable change as indicated by Jacobsen & Traux (1991).

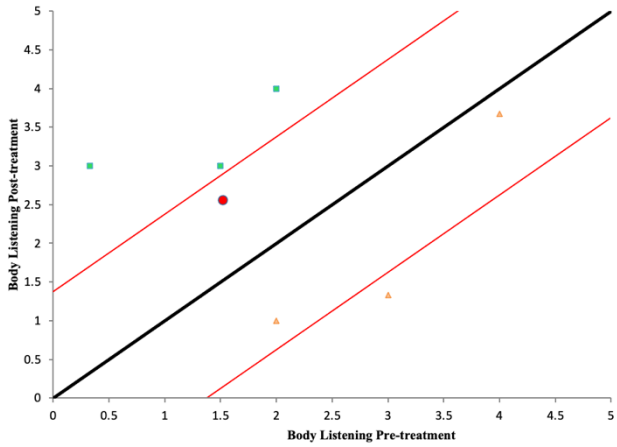
Figure 13

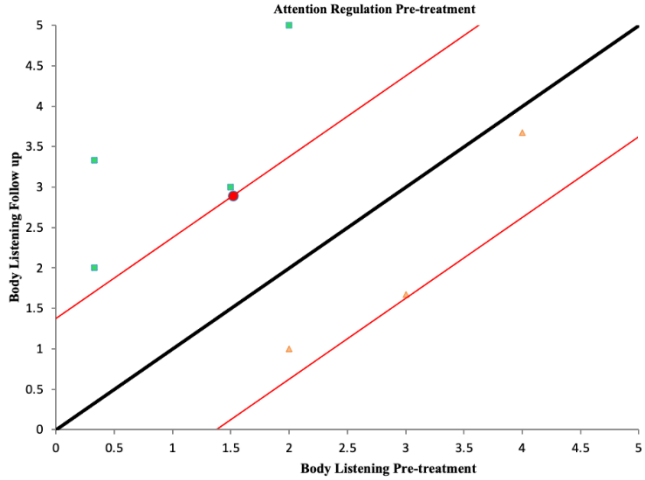
Scatter Plots of Baseline to Post-treatment and Final MAIA-2 Data Point Across Items

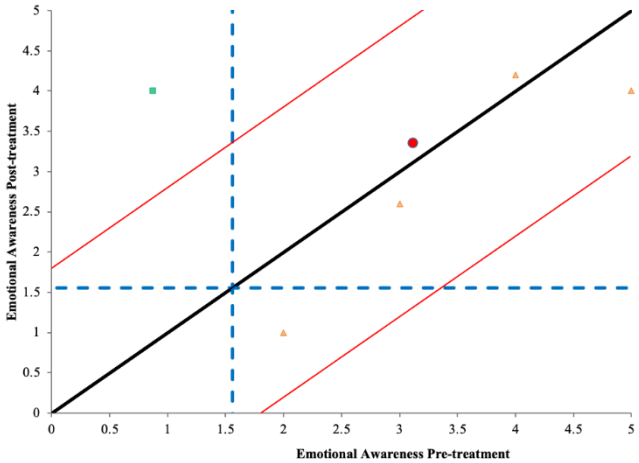


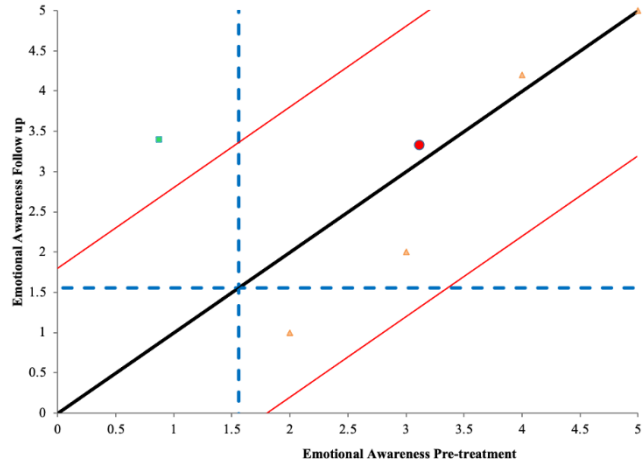

Attention Regulation Post-treatment
Attention Regulation Pre-treatment

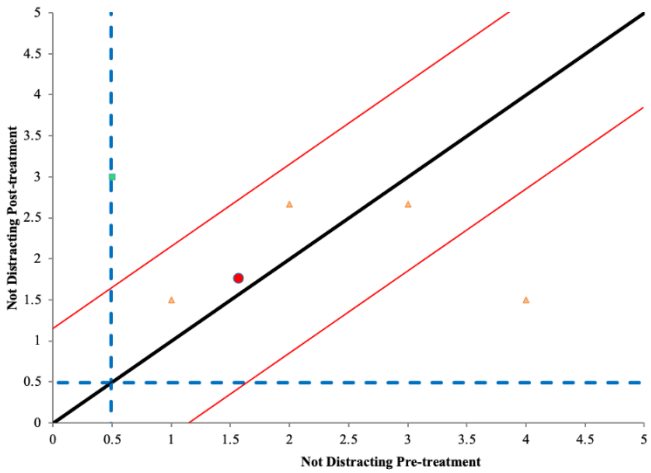

Attention Regulation Follow up
Attention Regulation Pre-treatment

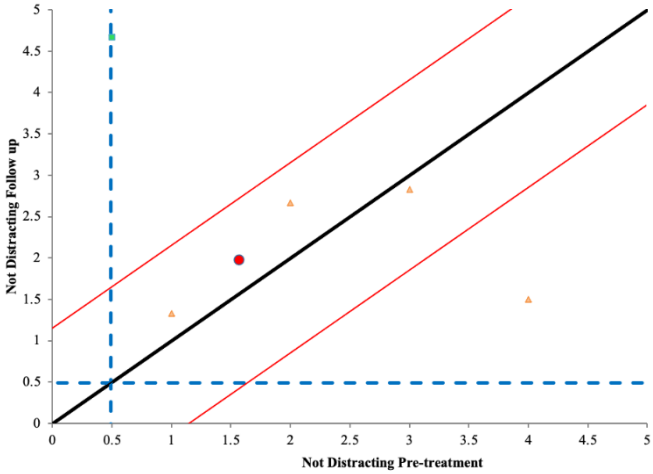

Body Listening Post-treatment
Body Listening Pre-treatment


Body Listening Follow up
Body Listening Pre-treatment


Emotional Awareness Post-treatment
Emotional Awareness Pre-treatment


Emotional Awareness Follow up
Emotional Awareness Pre-treatment


Not Distracting Post-treatment
Not Distracting Pre-treatment


Not Distracting Follow up
Not Distracting Pre-treatment

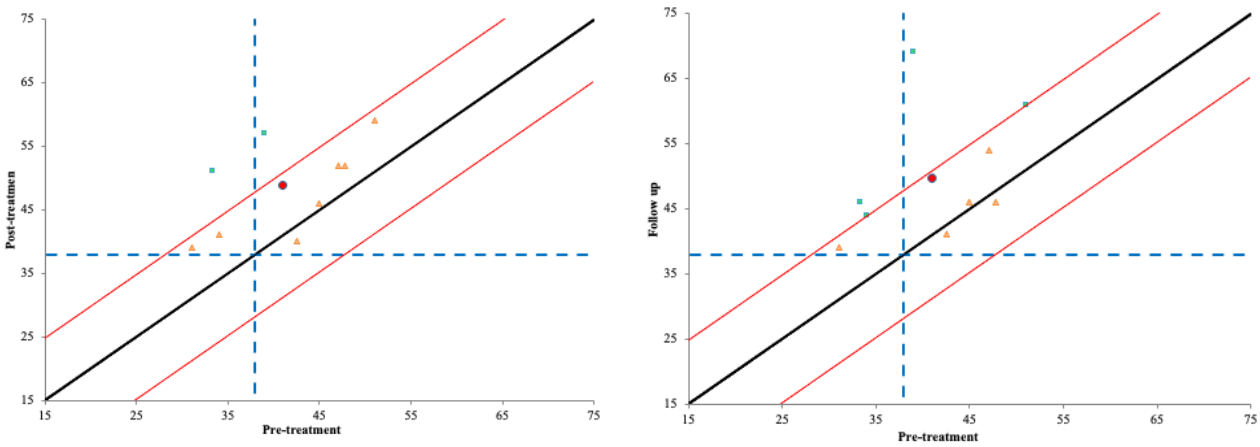
Note. Body listening graph does not have cut off score lines due to two standard deviations below the mean reported in norms falling below zero (Mehling et al., 2018).

Interoception (FFMQ-15)

For interoception, as assessed by FFMQ-15, two participants reliably improved (PtA, PtE) at the end of intervention and maintained gains through to final follow up data point. Four participants (PtA, PtE, PtF, PtH) demonstrated reliable change at final data point. No participants demonstrated a CSC. Results for FFMQ-15 are presented graphically in Figure 14.

Figure 14

Scatter Plots of Baseline to Post-treatment and Final FFMQ-15 Data Point Scores

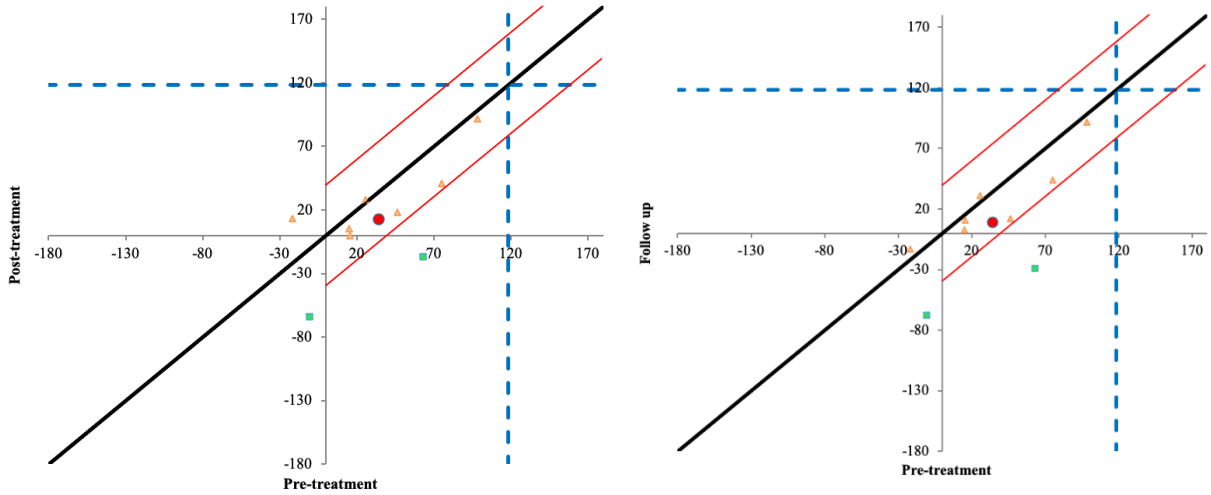


Emotion Regulation (DERS)

For emotion regulation, as assessed by DERS, two participants (PtE, PtH) met CSC at the end of treatment and maintained gains to their final data point. This was at the end of three weeks follow up for both participants. All other participants did not reliably change in either direction. Five participants (PtA, PtB, PtF, PtG, PtI) had reductions in their scores, though these were not significant. Results for DERS are presented graphically in Figure 15.

Figure 15

Scatter Plots of Baseline to Post-treatment and Final DERS Data Point Scores



Summary of Standardised Data

For interoception, four participants (PtA, PtE, PtF, PtH) showed RC on items across both measures (MAIA-2 and FFMQ-15). Six participants (PtA, PtE, PtF, PtG, PtH, PtI) demonstrated RC for at least one item of MAIA-2. Most participants (n = 4) showed RC for body listening and trusting items of MAIA-2 at follow up. Two participants (PtE, PtH) showed CSC for emotion regulation (DERS).

PtE responded to treatment best, reliably improving across all standardised measures in expected directions and also meeting clinically significant change for emotion regulation (DERS). PtC and PtD showed the least improvement post-treatment with no meaningful change detected on any standardised measures and PtD showing a reliable deterioration for Noticing subscale.

Acceptability

Seven participants anonymously completed the client feedback questionnaire. On average, participants scored 4.71 (SD= .49) for general acceptability and 4.07 (SD=.29)

across the six item questions. Higher scores, out of a maximum of five, indicate higher agreement with the acceptability item. Two items were reverse scored, burden and opportunity costs. Therefore, for these items, a lower score indicates higher acceptability. Mean scores for each item are displayed in Table 5.

Table 5

Acceptability of PVTT

Acceptability item	M (SD)
Affective attitude	4.71 (.49)
Burden	3.14 (1.46)
Perceived effectiveness	4.29 (.49)
Intervention coherence	4.43 (.53)
Self-efficacy	4.14 (.38)
Opportunity Costs	2.00 (.58)
Total mean score	4.07 (.29)
General Acceptability	4.71 (.49)

Note. M = mean; SD = standard deviation.

The highest score was for affective attitude, suggesting participants liked PVTT. Burden was most varied in ratings, with three responses rating PVTT as a huge or a lot of effort and the remaining four participants rating PVTT as a little effort. Responses to two open questions were recorded as part of the feedback questionnaire. Five participants answered these questions and verbatim quotes are presented in Appendix T.

Discussion

This randomised multiple baseline single case study evaluated the effectiveness and acceptability of PVTT for adults using a specialist weight management service. The main findings will be discussed in relation to the literature. Strengths and limitations are considered as well as future directions.

Interoception

Results indicate PVTT can target and improve interoception and has treatment durability. Idiographic measures provide evidence to the process of PVTT in supporting subjective body awareness. Idiographic results were supported by changes for six participants across standardised measures for interoception. Changes were most evident for attention regulation, body listening and trusting items. This provides encouraging preliminary evidence for the effectiveness of PVTT to target key interoceptive facets which are relevant for people living with obesity (Robinson et al., 2021; Todd et al., 2019; Willem et al., 2019, 2020). This is important as previous research has demonstrated that improving interoceptive accuracy without viewing the body as safe can lead to heightened emotional experience and emotion dysregulation in the form of EE (Calì et al., 2015; Dunn et al., 2010; Herbert et al., 2012; Pollatos et al., 2007; Willem et al., 2021). These findings corroborate previous research that has found training can support changes for attention regulation, body listening and trusting facets (Bornemann et al., 2015). Whilst Bornemann et al. (2015) did not find any changes for the noticing facet, the current study supports findings by Thomas et al. (2019) who targeted interoception in an obese population and did find changes on the noticing subscale. However, Thomas et al., (2019) did not find a difference between groups over time on the trust facet and given that the current study did not have an alternative intervention as a control group, whilst it is plausible to attribute changes to PVTT, specific mechanisms of change cannot be established. As with Thomas et al., (2019), it could be that the safety of the therapeutic

environment can support changes in trust for people living with obesity, though further research is needed to address this question.

Further, it is important to hold in mind that changes for attention regulation could be attributed to answering the questions rather than the intervention as practice effects for this item have been documented in non-obese samples (Höller et al., 2021). Further research should seek to have a comparison group who also engage in daily measures of attention regulation, without PVTT, to ascertain intervention effect for this facet.

Interestingly, a further four participants demonstrated significant improvements in body awareness VAS captured in the comparison of intervention and follow up phases. This accompanied a pattern of reduced variability for the second half of the intervention phase when sessions changed to at least fortnightly. There are two possible explanations for this. It could suggest that reduced frequency of sessions allows for increased practice and implementation in daily life. Previous research has demonstrated a link between out of session practice and changes in interoception (Bornemann et al., 2015) and generally, homework adherence significantly predicts outcomes in therapy (Conklin & Strunk, 2015). Alternatively, decreased variability and latency of change could be attributed to the nature of the intervention. Changes could be attributed to the honing of skills learnt later in the intervention. Future replications should seek to answer these questions through manipulating intervention session frequency and monitoring homework adherence. These two possible explanations have the intervention as a possible mechanism of change in common. In follow up, all participants were knowledgeable of PVTT techniques and had a therapy blueprint which included tailored plans for their everyday life beyond therapy. Arguably, therefore, such changes between intervention and follow up could be attributed to the intervention. In line with this thinking, it could be concluded that a total of eight out of nine participants

demonstrated improvements in body awareness as a result of the intervention. Further replication is required to substantiate these promising preliminary findings.

Interestingly, one participant showed significant changes across SCED and four standardised interoception items but, contrary to hypotheses, deteriorated for the trusting item. This participant was differentiated by her post-bariatric surgery status. Whilst poorer interoceptive awareness has been documented in gastric bypass patients (Beck et al., 2012), this was compared to the general population and not to those living with obesity who have not had surgery. Qualitative reports have found gastric bypass affects being able to trust inner body sensations for women (Groven et al., 2010). This could explain the divergent finding for this participant, though further research is needed to understand whether this could be attributed to surgery status and whether intervention adaptations for a post-surgery population are needed. For example, a longer intervention may be needed to foster trust in this subset of the population.

Emotion Regulation

It was hypothesised that PVTT would improve ER measured through idiographic ER, behaviour frequency and standardised measures. This hypothesis was supported as five participants demonstrated significant improvements in ER in SCED data and treatment gains were maintained for three of these participants. This is supported by two participants demonstrating CSC on the standardised measure of ER.

The inconsistencies in amount of participants that changed on ER VAS compared to standardised ER may be due to the use of the RCI (Jacobson & Truax, 1991). Whilst it still holds popularity amongst many researchers as a valid concept (Wise, 2004; Lambert and Bailey, 2012), other authors have voiced concerns (Blampied, 2022; McAleavey, 2021). Specifically, that RCI can overlook variability and richness in the data by only focusing on two data points, usually pre and post. Given the large standard deviation in population norms

for the DERS (Gratz & Roemer, 2004), substantial score changes are required to meet Criterion B standards. Therefore, whilst there is strong evidence for change in two participants, it is possible that meaningful change for more participants was overlooked by application of the RCI concept.

Results indicate that PVTT is effective at reducing maladaptive EE behaviours for most people and treatment effects hold durability. Although the current design did not stipulate EE as the target behaviour for reduction, it is noteworthy that this behaviour, in some form, was selected by the majority of participants. This supports research highlighting the prevalence of EE as a difficulty in this population (Konttinen et al., 2019; Vasileiou & Abbott, 2023; van Strien, 2018). Of the six participants who demonstrated behaviour change, three chose a variation of EE as their target behaviour which suggests that PVTT as an intervention to target EE requires further investigation. It could be that PVTT is an approach which allows the integration of mechanisms of change from a number of therapeutic approaches e.g., acceptance of emotions and behavioural change (Smith et al., 2023). Further research comparing PVTT to standard therapeutic modalities in the form of a randomised control trial could answer these questions. The current study provides some evidence for the durability of PVTT for EE, but longer term follow up is required since recent reviews have demonstrated EE intervention effects diminish at six month follow up (Chew et al., 2022; Vasileiou & Abbott, 2023).

Interestingly, for two participants, despite showing significant changes in ER across idiographic and standardised measures, they did not show any reductions in frequency of chosen behaviour. For these participants, it might be that changes in ER influenced other ER behaviours. This could be explained by the persistent nature of EE, its reliance as a strategy for people with obesity (van Strien, 2018) and its associated reward mechanisms that make it challenging to tackle (Dalton et al., 2013; Macht, 2008).

There are two participants who demonstrated minimal changes in relation to any measures and reportedly struggled to engage with practice outside of sessions. This could be formulated from a PVT perspective as the presentation of protective responses. In line with Ryland et al. (2021), it is possible that the participants' non-response to treatment may represent protective states of immobilisation that were so ingrained, it impeded their ability to enact behaviour change. It is also possible that comorbid depression in these participants impacted response. Non-verbal behaviours of depression such as reduced facial expression has been characterised as attenuated vagal activity (Fernandes et al., 2017) which could explain the reduced response in these participants. Depression is correlated with poor interoceptive accuracy (Pollatos et al., 2009) and research into interoceptive training for patients with comorbid depression have found that the Not-Distracting item of the MAIA-2 mediates response to intervention (Mehling, 2016). Therefore, it is possible that intervention adaptations specific to depression are required. Whilst another participant with co-morbid depression demonstrated change in outcomes, this could be attributed to comorbid anxiety which has shown to interact with the relationship between depression and interoception (Pollatos et al., 2009). Pollatos et al. (2009) found that higher levels of anxiety led to increased self-attention and therefore reduced the strength and trended towards reversing the direction of the relationship between depression and interoception. Therefore, differing presentations of depression may have moderated treatment effects, though further research is required to disentangle the influence of comorbidities.

Frequency of practice outside of sessions was not formally measured in this study. Subjective reporting when reviewing homework gave the therapist indications of homework engagement. It was noticed that those who struggled to complete homework and therefore did not implement PVTT techniques into their everyday lives, showed less changes in outcomes. This is in line with previous findings that has shown a link between out of session practice

and improvements on seven out of the eight MAIA scales of interoception (Bornemann et al., 2015), supporting advice around the practice of interventions outside of sessions to support changes in everyday life (Williams & Cullen, 2011). It would be interesting to measure, in future replications, out of session practice as a possible moderator in outcomes.

Adverse Childhood Experiences

It is understood that those with more ACEs may find it more challenging to engage with therapy due to disruptions to ANS functioning as a result of such experiences (Porges & Furman, 2011). Interestingly, those with the highest ACE scores responded well to treatment and were able to sustain changes through to follow up. It is possible that the safe environment of therapy, cultivated through a PVT lens, supported such effects (Geller & Porges, 2014). This would certainly be supported by the plethora of previous research into the mediating effects of therapeutic relationship on outcomes (Luborsky et al., 2002; Norcross & Lambert, 2011). However, the so called Dodo bird verdict has been criticised as a possible product of specific methodologies that overlook treatment type effects and diagnoses (Budd & Hughes, 2009; Luborsky et al., 2002). Replications with multiple therapists could further understanding of the role of therapeutic alliance in PVTT. It is also plausible that the attachment-based framework of PVTT offers an appropriate approach for people who have experienced ACEs (Porges & Furman, 2011). Whilst the ACE records specific experiences in childhood, what is not measured is the extent to which this has psychologically impacted an individual. Whilst prospective studies propose a risk factor (Dube et al., 2003; Felitti et al., 1998), this is not causal. Therefore, although there were high reports of ACEs in half of this group, the extent to which these accurately reflect psychological impact is unclear (McLennan et al., 2020).

Heart Rate Variability

As a measure of vagal tone, it was expected that HRV would increase as a result of the intervention, demonstrating a more adaptively functioning ANS. There was no evidence to support this hypothesis. Most participants demonstrated no changes in HRV across phases. Whilst there is evidence to support the validity and reliability of PPG methods to high control laboratory ECG (Giardino et al., 2002; Schäfer et al., 2013), a high level of poor quality data was collected in this study. A challenge of evaluating HRV and placing it within the wider literature, is the heterogeneity in data collection and analysis methods (Pham et al., 2021; Shaffer & Ginsberg, 2017). Participants were not asked to re-take the measure when given this feedback resulting in lost data. This method was chosen for the benefit of being able to remotely, easily and non-invasively collect data but null findings could represent a Type II error due to the amount of missing data. Whilst participants were instructed to take their HRV recording first thing in the morning, this was not always adhered to. This means that some participants may have already experienced stressors that affected their HRV and therefore day-to-day HRV is not comparable. Furthermore, data on factors such as menstrual cycles, which are known confounders for HRV, were not collected in this study which may explain variations in data (Brar et al., 2015). This is particularly relevant given the cis-women sample. Additionally, participants were not excluded on the basis of heart conditions or sleep apnoea which too, are known to affect HRV (Godfrey et al., 2019). Future research could consider incorporating such factors into exclusion criteria, though this will run the risk of reducing generalisability of findings to the target population.

Contrary to hypotheses, two participants showed significant reductions in HRV. For one participant this is consistent with a reduction in idiographic ER. This supports literature on the relationship between HRV and ER (Holzman & Bridgett, 2017). Specifically, low time-domain HRV is linked to loss of control eating (Godfrey et al., 2019) which could

explain the lack of changes in EE for this participant. However, given this was only one participant, further research should seek to replicate these findings to support generalisability. Significant reductions in HRV may suggest the intervention has a stress-arousal effect for these participants. It could be that focusing on the body and ER increased awareness of difficulties which led to a physiological stress reaction, though this would need further examining.

Acceptability

PVTT was rated as a highly acceptable intervention for this population across all respondents. In particular, affective attitude, how much the intervention was liked and how the participants feel about the intervention, was rated most highly. Affective attitude towards an intervention is of importance when assessing changes in interoceptive awareness. Bornemann et al. (2015) found that intervention-related changes on six of the eight scales of the MAIA were moderately correlated with the extent to which an individual liked the intervention. Although this was not assessed in the current study due to anonymity in the acceptability questionnaire, future research could account for this relationship. This supports previous research which has shown a preference for weight inclusive interventions in this population (Thomas et al., 2010). This is also in line with Medical Research Council's agenda for improving the acceptability of health care interventions (Craig et al., 2008; Moore et al., 2015) and has shown to improve implementation and outcomes (Diepeveen et al., 2013; Stok et al., 2016).

Interestingly, there was most variance in responses around burden with some perceiving the intervention as burdensome and others as low in burden. Whilst participants were instructed to view the intervention as separate from the overall research study, the burdensomeness of the SCED may have influenced responses. In relation to the intervention specifically, from session two all participants had at least three homework tasks and this rose

to up to eight tasks for some participants. Though collaboratively agreed in therapy, these understandably may have been perceived as burdensome, especially daily ANS tracking that asked participants to monitor ANS shifts up to six times a day. Furthermore, burdensomeness may have been interpreted as effort in sessions. Focusing on their body, for many participants, was a relatively new concept and was approached in sessions through practices such as body scans, expressive facial movements and breathing exercises. The act of practicing body-related techniques in sessions rather than talking may have seemed burdensome due to increased psychological demands for this group given the impact of weight stigma (Puhl et al., 2020).

Strengths and Limitations

A strength of the current study is its contribution to the field in empirically evaluating the use of a novel psychological therapy for people using specialist weight management services. To the author's knowledge, the study is the first to empirically test the applicability of PVTT for this population and to target interoception. The empirical findings demonstrate replication of an effect across at least three participants, across multiple baseline lengths which is in line with SCED standards (Horner et al., 2005; Kratochwill et al., 2010). This was further strengthened in weighted averages, which supports cross study comparisons (Hedges et al., 2012). Given the target population comprises people who inherently struggle with interoception and ER, these are promising findings. Although only a small proportion of audio recordings were rated using the adapted treatment fidelity measure, these all met acceptable compliance which adds weight to the notion that outcomes can be plausibly attributed to valid implementation of the PVTT manual.

The multiple baseline SCED means that maturation effects could be controlled for and as participants acted as their own controls, the nature of the design can overcome ambiguity about the generalisability of findings from between-group studies as it provides detailed

context about what works for what type of person (Kazdin, 2019). Collecting idiographic measures, one of which was chosen by the participant, and the flexible nature of intervention in tailoring strategies, supported meaningful engagement. Furthermore, the idiographic nature of monitoring EE overcomes criticisms of commonly used EE measures (Domoff et al., 2014; Vasileiou & Abbott, 2023). Idiographic measurement of body awareness also allows for individual interpretation, which is important since an individual's ability to detect heartbeat may vary from ability to detect gastric sensations (Khalsa et al., 2018). Idiographic analysis controlled for trends in baseline, improving confidence in attributing changes to PVTT. A follow up phase allowed treatment durability to be examined in the short-term. Furthermore, demonstrable reliable and clinical change on standardised measures adds to the credibility of the findings for some participants.

The approach of visual analysis has been subjected to criticism due to its arguably subjective nature (Kazdin, 2019). However, given the adherence to WWC and SCRIBE guidelines, the current analysis holds a level of objectivity (Kazdin, 2019). The current study sought to further control for this with the inclusion of a second reviewer and high inter-rater agreement evidences a high level of reliability. The main researcher and therapist acted as the main analyst which is promoted as improving quality of analysis through bottom-up enquiry (Parker & Vannest, 2012).

The sample is biased in terms of gender and ethnicity with all white and female participants. The gender bias is consistent with the increased prevalence of obesity in women and that women tend to be more help seeking than men and therefore users of weight management services (Kanter & Caballero, 2012; Thompson et al., 2016). Whilst this impacts generalisability, it is worth noting that the sample size exceeds previous SCEDs in the field which have had five and four participants respectively (Abrahamsson et al., 2018; Sadeghi et al., 2010) adding to the power of the study. Moreover, the broad inclusion criteria supports

generalisability to the target population. In relation to power, a limitation of this study is that those who completed a seven day baseline did not yield enough data points for sufficient power according to Shadish et al. (2014). However, these participants provided enough data points to meet WWC "standards with reservations" (Kratochwill et al., 2010; WWC, 2022) and previous research has found that baselines with six to seven data points yielded a bias of only around 5% (Barnard-Brak et al., 2021).

Missing data in this study was treated as missing at random (MAR; WWC, 2017). This may have overlooked psychological explanations for non-completion. It could be proposed that VAS were not completed by participants when there were high levels of emotion dysregulation or increased frequency of chosen behaviour which may have triggered feelings of shame. For example, due to the role of internalised weight bias and shame in EE (Braun et al., 2021; Wong & Qian, 2016), participants may have abstained from reporting on days when behaviours were particularly high. Future research should look to measure factors of shame and weight stigma to explore the relationship these have with treatment and outcome measure engagement for this population. Alternatively, computational analyses could have been applied to the data to either carry forward the final data point or generate computed averages to increase data points (Peng & Chen, 2018). Such methods should be considered a priori in future research.

The treatment fidelity scale was limited as it is an unvalidated measure. This is expected, given the infancy of the current intervention. However, efforts were made to use a well validated measure as a framework and fidelity was assessed by an experienced supervisor. Although treatment fidelity was assessed throughout intervention in weekly supervision and sharing of audio clips, formal ratings of full sessions were based only on four sessions. These were randomly selected to overcome bias but treatment fidelity of the remaining 41 sessions cannot be accounted for.

Clinical Implications

Clinically significant changes in relation to ER indicate that PVTT is an effective intervention to target ER for people living with obesity. This contributes to the theoretical understanding that improving interoception, specifically the ability to trust bodily sensations for people living with obesity, supports more adaptive ER (Fernandes et al., 2018; Smith et al., 2023; Willem et al., 2021). ER and the trust facet of interoception have been posited as important therapeutic targets for people living with obesity (Fernandes et al., 2018; Willem et al., 2021) and this study has provided preliminary evidence of the effectiveness and acceptability of PVTT to target these areas.

The ability to discern the effect of PVTT on specific interoceptive facets supports understanding of the mechanisms of PVTT and highlights possible transdiagnostic applications of the intervention which is line with interoceptive research agendas (Khoury et al., 2018). Specifically, being able to target the body listening and trust subscales holds clinical value for this population as cross-sectional data shows deficits in these areas (Robinson et al., 2021, Willem et al., 2021). The findings indicate the importance of greater attention to physiology in psychological interventions for this population as a precursor to effective ER. Whilst physiology is acknowledged in other evidence-based treatment such as a CBT, the importance and priority placed on physiology in PVTT is a defining factor that impacts outcomes.

In terms of treatment delivery, attention should be given to the sense of safety cultivated in the therapeutic space to facilitate trust when attending to bodily sensations. The online nature of the intervention is in line with increased popularity of online interventions for service users (Hutchings, 2020). Further, this could have beneficial cost implications in reducing resources (Smith et al., 2023). Online sessions are preferred by some therapists and service users alike as this mode can support comfort such as not having to wear a mask

(Shklarski et al., 2021). In fact, receiving and delivering therapy from one's home may support ER as the environment can be set up to be conducive to the individual's autonomic regulation (Graham et al., 2015). CBT for this population has been criticised as time intensive (Smith et al., 2023). The current study provides evidence of change following six sessions of PVTT which holds promise for increasing access to psychological therapies and reducing waiting times, as it could be considered a brief intervention. Furthermore, the manualised nature of the intervention, with accessible and easy to understand behavioural strategies could have implications for being delivered by less specialist healthcare professionals, again increasing access (Smith et al., 2023).

PVTT supports progression towards adopting weight-inclusive approaches for people using specialist management services by targeting non-weight related health outcomes (Bacon, 2010; Bacon & Aphramor, 2011; Hunger et al., 2020). This makes a valuable contribution towards addressing weight stigma which is known to negatively impact health of those in bigger bodies (Puhl et al., 2020). Furthermore, as the intervention works beyond symptomology this is relevant for this population who often have comorbid mental health diagnoses (Weiss et al., 2020).

Future Research

Whilst this study has provided promising initial findings of the effectiveness of PVTT for people living with obesity, further replication is required to validate findings. To improve confidence in the validity of PVTT effects, replication across cases, research groups, therapists and settings is necessary (Horner & Spaulding, 2010). Ultimately, this would allow for the inclusion of SCED in meta-analyses once replication has occurred across at least five studies that meet WWC standards, three different research groups and three different institutions to gain a combined number of 20 cases (WWC, 2017). The current study provides an important first step in this process.

The pattern of change occurring in the second half of the intervention and being realised statistically in the intervention to follow up phase change is worth further investigation. Future research should test hypotheses related to latency of change and optimum frequency of session delivery. Subjective feedback from participants was a preference for fortnightly sessions to allow time for implementation between sessions. It would be beneficial to measure this factor to compare against previous findings on the importance of out of session practice on outcomes (Bornemann et al., 2015; Williams & Cullen, 2011).

Conclusion

To summarise, this study provides new evidence of the potential of PVTT as an acceptable and effective intervention for adults using specialist weight management services. PVTT offers a weight inclusive approach that targets key health related outcomes, overcoming more traditional interventions that can serve to perpetuate weight stigma. This was a proof-of-concept study of the applicability of PVTT to an obese population to improve interoception and ER and overall provides evidence that warrants further research and replication.

Chapter IV: Integration, Impact and Dissemination

Integration

Reflections on the Process

I have long held a personal interest in understanding and meeting the clinical needs for people living with obesity and a desire to contribute and further the research field. I was aware that PVT was being used clinically with this population, despite there being little evidence of its effectiveness. The clinical use of PVT made theoretical and intuitive sense and clinicians were realising its anecdotal effectiveness with this population, especially in relation to supporting people to feel safe in their bodies. However, given the lack of evidence to support its use it felt like an important area to subject to scientific enquiry.

When the research project was in its development stages, I had intended to conduct a systematic review on the use of PVTT. However, from conducting initial literature searches it became apparent that there is a scarcity of empirical work evaluating the use of PVTT. I realised I had to take a step back in the scientific process and a conceptual review was needed to bring together the fields of PVT and interoception for people living with obesity. The conceptual review aimed to synthesise and evaluate current understanding to provide the theoretical foundations of the applicability of PVTT to this population. The CR addressed challenges in relation to measuring interoception, specific facets related to this population and proposed a model of PVT could be applied to this population. The CR highlighted important gaps in the research in relation to examining the acceptability and effectiveness of PVTT to address interoception and ER. This paved the way for the empirical paper (EP). Given the infancy of PVTT, the CR informed the design of the EP which adopted a SCED as a methodologically robust approach to answering the research questions.

Study Design

I was initially concerned that the online nature of the intervention may impact co-regulation due to evidence that interpersonal cues are reduced as a result of remote therapy (McBeath et al., 2020). This is of relevance to PVTT which is built on an attachment framework, emphasising the interpersonal cues between client and therapist to be imperative to co-regulation and success of the therapy (Dana, 2018; Geller & Porges, 2014). As a result, I made a conscious effort to ensure that my upper body, and hand gestures could be seen on video to support regulation. Despite initial concerns, I did not feel that co-regulation was negatively impacted by the online format of the intervention. This was corroborated by verbal feedback from participants who regularly reported feeling seen and understood and the qualitative feedback such as "I was very comfortable with Alex, she was very warm and caring. I was able to be very open and vulnerable with her" (Feedback 4, Appendix T). I was moved by the strength of the therapeutic relationship that I built with participants in such a short time and felt privileged to witness their vulnerability, trust in the relationship and intervention and reported gains beyond those picked up by the outcome measures. Therefore, I believe the online format to be a further benefit of the design, in demonstrating the effectiveness of online therapies for this group which could serve to increase access to psychological therapies (Puente & Martínez-Marcos, 2018). This is of relevance to this population who have mobility issues which can hinder in person attendance at appointments and can reduce travel burden to national specialist sites (Lohnberg et al., 2021).

Given the nature of SCEDs to repeatedly collect data over a number of phases (Kazdin, 2019; Morley, 2017), I ended up with a large amount of data. At times, I felt great pressures on my time juggling the demands of placement, academic work, weekly PVTT sessions, checking on daily adherence with measures and sending reminders to participants. When I had collected all the data, I initially felt daunted as I set out to apply a novel analysis

method to me. However, with the guidance of Morley (2017) and the doctorate course team, I relished the opportunity to work with the data in a different way, moving away from familiar group comparisons. The richness of the data and the visual analysis approach allowed for a 'bottom up' intimate understanding of the findings and provided deep insights into clinical and statistical changes (Parker & Vannest, 2012). At times, I felt I could write a whole thesis on each participant, and often felt constrained by the word count as I wanted to bring the person into the data whilst being mindful of the constraints and reporting guidance.

Recruitment

The clinical team at the recruitment site were extremely helpful in identifying suitable cases and I quickly had several potential participants. I had a number of opportunities to present the research to the clinical team which fostered this relationship and kept the research at the forefront of clinician's minds. This was further supported when I started a six-month placement at the recruitment site in which I could directly recruit participants when meeting new referrals to the service. From the start of the recruitment period, I managed an average rate of one consented participant per week solely through the support of the three-person psychology team. This meant that I did not have to initiate other forms of recruitment such as sending advertising posters via email to all service users. I had two participants who were recruited and then either dropped out or no longer met eligibility criteria. I was able to quickly fill these available slots by new participants within the study time frame to ensure I met the initial recruitment targets required for power.

Experts by Experience Involvement

I was keen to have experts by experience (EBE) involved in as many aspects as possible of the empirical study to ensure the research from design to dissemination was relevant and meaningful to the population. I contacted a number of third sector organisations and was pleased to meet with two EBE from Obesity UK. I worked alongside these two

individuals who both have experience of specialist weight management services in the UK and living with obesity. From considering the 'ladder of participation' (Arnstein, 1969) I wanted to ensure EBE involvement was beyond tokenism and met the remits of the 'participation step' so that their feedback and input could influence changes in the study design, ensuring more equity in terms of power.

Their input on reviewing documentation and general design considerations was invaluable. This led to a number of changes in wording, formatting and design considerations. For example, re-wording the visual analogue scale questions and devising the wording for the client feedback form using the validated framework (Sekhon et al., 2022). Their feedback on the promise of the intervention and the weight inclusive focus was also encouraging when in the early stages of the research project.

I would have liked to increase the level of EBE involvement through more co-production however I was limited by the expenses allowance, which in line with National Institute for Health and Care Research public contributor payment policy (NIHR, 2022), allowed only two hours of EBE support. This meant I had to be concise and efficient in the time with EBE. Future research would benefit from more funding to address this potential limitation in the extent of EBE input and that the input of two people may not be representative of the wider obese population.

The intervention manual was reviewed by a range of professionals with experience of working clinically with PVT and specifically with people living with obesity. This served to ensure the intervention was clinically meaningful, relevant and sensitive to the needs of the population. For instance, carefully considering the wording and rationale around chewing gum as a regulation technique rather than as a distraction, body avoidance or alternative to meeting hunger needs.

Use of Terminology

Language used at all points of care can impact outcomes for people living with obesity and the wider healthcare system (Albury et al., 2020). Therefore, I was keen to have EBE input on the terminology used throughout the study. The term 'living with obesity' has been used to denote obesity as a disease with aims to reduce stigma by moving away from the view of obesity as a lifestyle choice (Wilding et al., 2019). However, classification of obesity as a disease has been criticised to eliminate autonomy and reduce empowerment that people have in their own health (Wilding et al., 2019). I also have reflected critically that the disease narrative, which is underpinned by a medical dogma, could serve the interests of pharmaceutical companies that can springboard off this narrative to sell weight loss drugs that overlook the contribution of psychosocial factors.

Whilst the term 'living with obesity' was used throughout the research reports as advised by EBE input, I consulted each participant individually to ask them what terminology they would prefer and used the participants language throughout our contact. This is in line with policy that recommends person-first language for obesity (American Medical Association, 2017). Research into the preferences of patients around terminology have leaned towards more neutral terms such as unhealthy weight rather than fat or morbidly obese (Auckburally et al., 2021; Puhl et al., 2013;). This provides an opportunity for addressing weight stigma through patient choice around terminology and language and aligns with lobbies for clinicians to move away from using culturally stigmatising terminology (Flint et al., 2017).

The Intervention

Whilst I had a keen interest in this area, it was my first time working clinically with people living with obesity and revealed me to high levels of internalised shame and fat phobia in participants. When practicing some of the body scan exercises and supporting

people to bring attention to their body, I noticed that this felt too painful for many people as negative thoughts and shame about the body were overwhelming. In response to this, I learnt to flexibly adapt body focused exercises asking participants to focus on more neutral and safe areas such as tightness in the shoulders, temperature changes and tension in the head. I valued the support of my supervisors in guiding my practice and offering alternatives to ensure the safeness of the therapeutic space for participants. I was fortunate enough to align the majority of the intervention work with my six-month placement at the recruitment site. This experience enriched my theoretical and clinical knowledge of working with this population.

In line with a PVT way of working, I was conscious of how my own body was regulating and my felt sense of co-regulation with clients when they displayed distress. Therapist feelings towards clients have shown to mediate therapy outcomes (Westra et al., 2012) and must be managed in supervision. I'm conscious that the therapist, themself, must be in ventral vagal to support PNS activation in their client (Ryland et al., 2021). Therefore, I was mindful to offer a safe and contained presence and to do so, had to use behavioural strategies such as slow-paced breathing before sessions to activate my own PNS. This was pertinent given my own stress levels in juggling multiple course and placement requirements. As such, the intervention and thesis process felt an immersive one as I have been teaching others to regulate their nervous systems whilst also personally implementing such techniques into my own life. I felt that through having a personal sense of the impact of the techniques on my own body, I was able to more authentically share the techniques and Socratically support learning for participants. This is supported by empirical work to show that self-care behaviours can widen the therapist's 'window of tolerance', inhibiting release of the vagal brake (Baldini et al., 2014) which can foster a sense of safety and containment in the therapy space (Badenoch, 2018).

Throughout the empirical study I noticed a tension between my clinical and research hats. With my clinical hat on, I wanted to provide compassion and understanding around the burdensome nature of daily measures. Though my researcher hat urged me to encourage participants to adhere to outcome measure completion. I often had to tow this line and respond flexibly and sensitively to the needs of the client and the needs of the research project and honoured transparency around this with participants.

When the intervention phase came to an end, I was struck by the expression of feelings of loss and sadness from many participants. This made me reflect on this specific population of people who are seen by services for their weight and physical health yet have emotional and psychological needs. It is a group of people who often fall between the gaps of services. I have witnessed long waiting lists and under resourced psychology services which impact psychological therapies provision in weight management services. This group of people often do not meet the threshold in terms of clinical symptomology that is necessary for specialised therapies beyond six sessions of guided self-help provided in increasing access to psychological therapies (IAPT) services and therefore struggle to access psychological support required. This was also evident in the recruitment process where many people expressed a strong desire to have access to some kind of psychological intervention.

Participants fed back that fortnightly sessions were preferred. For example, one participant noted in the feedback "Longer sessions between each face to face sessions would have been beneficial" (Feedback 1, Appendix T). This was because it gave participants more time outside of therapy sessions to try out, practice and implement strategies into their everyday life. Since research has demonstrated the importance of homework adherence in outcomes (Conklin & Strunk, 2015), further research would do well to investigate this mechanism in relation to PVTT. I also wonder whether further titration of sessions, such as

moving to monthly at the end, could mitigate the feelings of loss at the end of the intervention by supporting more autonomy and empowerment with the therapeutic techniques.

Impact

Clinical Impact

The empirical findings provide promising evidence that PVTT can support interoception and ER in a format that is well liked, makes sense and was perceived to be effective. These findings are encouraging as they are in keeping with other studies to show that a psychological intervention can modulate interoception (Bornemann et al., 2015) and this is applicable to a population that has established interoceptive difficulties (Robinson et al., 2021). The online format of the intervention increases access as many individuals have to travel across counties to be seen at specialist centres as well as supporting those who find it difficult to travel e.g., mobility or financial constraints. These preliminary findings support anecdotal case work and the applicability of PVTT to this population which has a clinical impact due to the high levels of emotional suppression in this population (Fernandes et al., 2018) and the need to therapeutically address interoception (Robinson et al., 2021; Willem et al., 2020).

Given the high levels of acceptability reported in the empirical study, it is possible that understanding patients through a PVT lens could have wider reaching clinical impact for non-psychological clinicians. In weight management services, allied health professionals including physiotherapists, nurses and dieticians, support behaviour change. Understanding resistance to behaviour change through a PVT lens (Ryland et al., 2021), how to support co-regulation and a trusting therapeutic relationship or how to support self-regulation techniques could further the breadth of work and improve outcomes and patient experience of care from other allied health professionals. My own experiences of applying PVTT regulation strategies could also be of benefit to health professionals across the service to support their personal

psychological wellbeing. The link between self-care amongst health professionals and improving patient outcomes is well evidenced in the literature (Posluns & Gall, 2020; Riegel et al., 2021) and PVTT techniques could contribute to this growing field.

The CR offered a view on the applicability of PVT to the psychological aspects of obesity. This could have further clinical impact in relation to understanding upper gastrointestinal problems through the lens of PVT (Kolacz et al., 2019). This could offer a more holistic and compassionate stance from medical staff.

Academic Impact

The CR summarised cross-sectional findings which have demonstrated impaired interoception in people living with obesity and posited interoception and ER as important therapeutic targets (Robinson et al., 2021). Elsewhere, within a healthy population, interoception has shown to be open to modulation through training (Bornemann et al., 2015), though this has not yet been applied to an obese population. PVTT has been posited as a beneficial therapy for people (Dana, 2018) though this has yet to be subjected to thorough scientific enquiry. The CR sought to bring together these fields, to integrate current knowledge and highlight possible areas for research. This contributes to the academic field in synthesising the latest evidence and understandings of interoception, ER and PVT and its applicability for people living with obesity.

The CR outlined a clear gap in relation to interventions for interoception for people living with obesity and empirical studies of PVTT. The ER sought to address this gap by examining the acceptability and effectiveness of PVTT for improving interoception and ER through robust scientific methodology, utilising SCED. This may increase interest and attract further research attention to further the development of psychological interventions drawing on PVT to support this population. The findings from the ER warrant further research and should be replicated in larger samples and across clinical sites and therapists. It would be

interesting to further understand the process of change to support tentative hypotheses about the mechanisms of change and the important role of trust in the body.

Societal Impact

The development of an intervention to support the psychological wellbeing of people living with obesity can have economic benefits. Current economic burden of obesity in the UK is positioned at £6 billion (DHSC, 2022). Finding effective interventions to support the health of this population is imperative. However, approaches that have focused on weight as the primary outcome have raised ethical concerns for being based on poor evidence, lacking community engagement, and overlooking the cause of the problem (Allen-Scott et al., 2014). These approaches ignore the impact of weight stigma and anti-fat bias on individuals (Puhl et al., 2020). Addressing anti-fat bias in society must adopt a multi-faceted systemic approach to support societal and cultural shifts. As scientist-practitioners, clinical psychologists have a responsibility to enact this change in their clinical and academic work. Developing weight inclusive interventions can serve towards this aim and contribute to addressing and challenging anti-fat biases. My hope is that the current study contributes to the evidence for weight inclusive interventions, supporting this cause and ensuring adherence to ethical standards (Tylka et al., 2014).

The CR and ER highlight the contribution of psychological factors in obesity and eating behaviours. This substantiates calls in research and clinical arenas to address obesity and eating behaviours in a multifaceted manner (Hunger et al., 2020; DHSC, 2007). This has potential societal impact due to the recent approval, distribution and promotion of weight loss drugs in the NHS that have received an inordinate amount of press coverage and public interest (Gallagher, 2023). Although it is important to recognise the benefit this may offer to some patients, these pharmaceutical interventions could perpetuate a societal narrative that assumes all eating behaviours are hunger related. As highlighted in the CR, hunger itself is

complex and relies on being able to accurately identify hunger and satiety signals, trust these signals and respond adaptively (Herbert, 2020). Reasons for eating extend beyond hunger, with emotions significantly impacting eating behaviours for this group (Vasileiou & Abbott, 2023). Therefore, a pharmaceutical approach is reductionist as it overlooks the complexity of eating behaviours and could contribute to societal stagnation in change around weight bias (Charlesworth & Banaji, 2019). This has raised concerns for me which I raised with the medical officer at Novo Nordisk who produce the main licenced weight loss drug in the UK to discuss their approach and understanding of the psychological factors related to weight loss drugs for obesity. They have ongoing clinical trials as the psychological impact of these weight loss drugs is not yet fully understood. The current study provides further evidence of the importance of considering psychological factors in the understanding and treatment of obesity.

Dissemination

Research Community

The CR and ER will be prepared for submission to peer reviewed journals. Obesity Research and Clinical Practice, Obesity and International Journal of Obesity are some of the relevant journals that will be considered. A poster presentation will be prepared for submission to the British Obesity and Metabolic Surgery Society (BOMSS) annual conference 2024. This conference is attended by allied health professionals, medical professionals, researchers and policy makers in the field of obesity and will support wide reaching, national dissemination and discussion of the research.

Clinical Community

One case from the EP was presented at the National Complex Case Forum for weight management and bariatric psychologists on 25th April 2023. This monthly forum is attended by bariatric psychologists across the UK and stimulated interesting discussion into the PVT

formulation and intervention for this particular case as well as the wider reaching implications of the use of PVT. The use of PVT with this population was very well received by the audience and I have been invited to share the PVTT manual with services as well as support training in the use of PVT with this population.

The results of the EP were disseminated via online oral presentation to trainee clinical psychologists, course staff and academic supervisors at Royal Holloway, University of London. These findings will also be disseminated to the clinical team within the recruitment site. Finally, the thesis will be publicly available on the university system, Pure with the hope that it can be used to support future research in the field.

Public and Service Users

In line with HRA best practice guidelines (2023), all participants who have consented to being contacted in this way will be provided with a lay summary of the findings. A summary of the research will be circulated via Obesity UK social media channels and there are plans to present at one of their monthly support groups.

It is hoped that dissemination via these multiple avenues to researchers, clinicians, the public and service users will stimulate further research, interest and awareness into the application and benefit of PVT for people living with obesity.

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Appendices

Appendix A

Participant Information Sheet

Ashford and St. Peter's Hospitals
NHS Foundation Trust

Participant Information Sheet
Talking therapy for body awareness and managing emotions for people living with obesity: a multiple baseline study

My name is Alex Phillips, and I am a Trainee Clinical Psychologist doing a doctorate in clinical psychology at Royal Holloway, University of London. As part of my doctorate, I am carrying out a study to evaluate a talking therapy for people living with obesity. I would like to invite you to take part in this research project.

Before you decide whether you want to take part, it is important for you to understand why the research is being done and what your participation will involve. Please take the time to read the following information carefully and discuss it with others if you wish.

What is the purpose of the study?
People living with obesity can find it difficult to notice and cope with emotions. This can lead to unhelpful ways of coping such as emotional eating which can contribute to difficulties with weight. Previous research has shown that talking therapies can help people manage emotions.

However, these therapies overlook the role the body plays in emotional experience. The autonomic nervous system (ANS) is the system in your body that makes you feel calm, frightened, or numb. It is your ANS that starts your heart beating fast, makes you shake or breath fast when you are annoyed or anxious. It also makes you feel calm, content, and safe. It picks up on things inside your body and the outside world. It can do this so quickly that sometimes you won't even have noticed what has set it off.

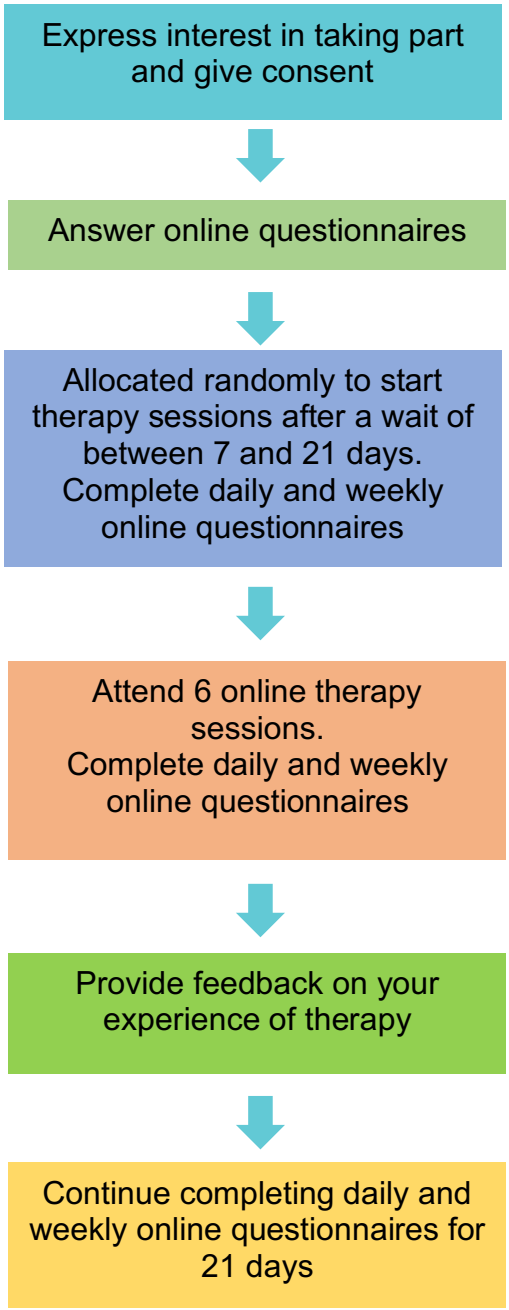
The ANS is always looking for threat, especially if difficult things have happened to you in the past. It is really good at jumping to a conclusion from only a small amount of information, deciding there's threat and triggering a response in your body so that it can help keep you safe. Many people, including people living with obesity, aren't very aware of what is happening in their bodies. They have become disconnected from the body's signals. The problem isn't that your ANS changes what is going on in your body, rather it is that you are out of the habit of monitoring your bodily sensations and/or that you don't have enough ways of changing how you feel. By knowing what is going on in our bodies we have more choice as we can decide how to manage the emotion we are experiencing.

In this study, we are looking to see whether using this understanding of the ANS can improve talking therapy. The therapy aims to help you notice what your ANS and body is doing so you can choose how to manage your emotions.

We want to make sure that this therapy is useful to people and understand how good it is at helping you notice and manage your emotions. Therefore we will ask you to complete questionnaires on noticing your body and emotions. We will also ask you to track your heart rate variability (HRV). HRV is a way of measuring how responsive the ANS is. I will also be asking you to complete a questionnaire about how you found the therapy so we can understand your experience of therapy.

Why have I been invited to take part?
You have been invited to take part as you are a current service user at Ashford and St Peter's Hospital Specialist Weight Management Service.

What will happen if I take part?
The flow diagram below summarises what will happen to you if you decide to take part and is followed by a more detailed description.



If you choose to take part in this study, you will be asked to commit to the overall study for up to **16 weeks.** There are three phases to the study: baseline, therapy and follow up. Before you begin the baseline phase, you will complete a questionnaire that asks about any difficult experiences in your childhood. This is so we can understand whether there were any significant life events in your childhood that may have impacted how your ANS looks for threat.

During all three phases, you will complete a daily questionnaire (three questions) that asks about your body awareness and emotions. You will also take a daily recording of your HRV using a mobile phone app. We know that things can change day to day so daily measures are helpful to see how things are on average for you. These daily tasks take less than 5 minutes. During all three phases, you will complete three short questionnaires once a week. These questionnaires ask you about your awareness of your body, emotions and managing emotions and take around 15 minutes each week. All the questionnaires are completed online.

You will be randomly allocated to a **baseline** period of 7, 14 or 21 days. This will be randomly assigned using a computer random number generator. This means you have an equal chance of being allocated to any of the three baseline lengths. The overall study length and commitment required depends on which baseline length you are allocated to. You will not receive any therapy during the baseline phase. During this phase you will complete daily and weekly questionnaires. This is so we can understand how things are for you usually before any treatment starts.

Following baseline, you will begin the **therapy** phase when you will receive 6 one-to-one talking therapy sessions with myself, a trainee clinical psychologist. Session times and dates will be agreed between you and the therapist. Therapy sessions will take place over video call, so you do not need to come into the clinic in person for your sessions. The 6 sessions will take place within a maximum of 10 weeks.

The therapy sessions will help you understand how your ANS works and teach you some techniques to bring awareness to your body and manage emotions. For example, one technique is breathing exercises. We will practice techniques together in the sessions and then you will continue to practice these outside the sessions.

During therapy I will ask to audio record sessions. A random sample of the recordings will be listened to, to assess the quality of the delivery of the therapy, not to assess you or the content of the therapy. This will only be done by the lead supervisor and then recordings will be permanently deleted. Audio recording of sessions requires your consent and you do not have to agree to it. If you would not like your therapy sessions to be recorded, this will not affect your ability to take part.

After you have completed the six sessions of therapy, you will complete a feedback form which will ask you how you found the therapy. This is so we can fine tune the therapy to be more relevant and user friendly where necessary for future users.

Finally, you will complete a **follow up** phase where you will continue to practice the techniques independently and continue to complete daily and weekly measures for three weeks. This is so we can see whether the therapy's effects are maintained over longer periods of time, not just until the end of therapy.

What do I need to take part?
You will need a computer/tablet/phone with internet access to take part in this study. This is because all the questionnaires are online. The therapy sessions will also take place over video call. Therefore, it is important that you have a space at home that is private and free from distractions for the therapy

sessions. We ask that you organise your commitments (e.g., childcare) in advance of the therapy phase so that you can fully focus on the therapy. We also ask that you have a smart mobile phone which will be needed to receive reminder messages to fill out the questionnaires and your appointment times. A smart phone (android or apple) will also be needed to download the app to measure heart rate variability. Unfortunately, we cannot offer the study to people without internet access or a smart phone.

Do I have to take part?
No, it is completely up to you whether you choose to participate in this study. If you decide to take part, you may withdraw at any time without having to give a reason. Your decision whether to take part or not will not affect your treatment and care in any way.

If I choose to participate, will my participation be kept confidential?
If you decide to take part, all your information will be kept strictly confidential. You will be allocated a participant ID and all data will be recorded using this ID so you will not be identifiable from the data. All data will be stored on secure University and NHS systems and will be password protected. Only the research team will have access to this data. Data will be stored securely for ten years after the completion of my degree. The purpose for this is so the data is available if there are any appeal procedures or examinations queries. All the data will be destroyed after this time. The clinical team at Ashford and St Peters Hospital will be informed of your participation. This will not affect your treatment with the team. If I become concerned about your safety or the safety of others during the study, it is routine practice that I share this information with your clinical team and potentially other services such as your GP or A&E. Where possible, I will try to discuss this with you first.

What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason. It will not affect the care you receive. The information already collected however will be kept confidential with the research team. We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the information we hold about you. If you agree to take part in this study, you will have the option to take part in future research using your information saved from this study. Any future study will be reviewed by an independent group of people called a Research Ethics Committee in order to protect your safety, rights, wellbeing and dignity. The information will be kept in a safe database at Royal Holloway University of London.

Where can you find out more about how your information is used?

You can find out more about how we use your information at www.hra.nhs.uk/information-about-patients/ or by asking one of the research team by emailing me on Alexandria.phillips1@nhs.net or contacting the Custodian of the Data, Dr Katie Ashcroft, katie.ashcroft@rhul.ac.uk.

What are the possible benefits of taking part?
We cannot guarantee that participating in this study will result in direct benefits. However, you may find the psychological therapy helpful in supporting you to identify and manage emotions. You will be contributing to a better understanding of the value of psychological therapy for people living with obesity and this may benefit other patients using specialist weight management services in the future.

What are the possible risks of taking part?
It is not expected that you will encounter any risks as a consequence of taking part in this study. Some questionnaires ask about sensitive issues and therefore might cause you some discomfort. Although you complete a questionnaire about childhood experiences, the therapy itself will not be focused on any of these experiences as it focuses on how you are feeling in the here and now rather than what happened to you in the past. If at any point you feel distressed when completing questionnaires, please let me or someone from the research team know and you may terminate the questionnaire or omit parts if you wish.

During the talking therapy you may find it uncomfortable to pay attention to bodily and emotional states. You will be supported by the therapist who is well trained and experienced in supporting people in clinical settings. A full debrief will be provided at the end of the study with signposting to further support if you need it.

This study requires a significant time commitment. I will ask you to complete daily questionnaires that take 5 minutes and weekly questionnaires that take 15 minutes for up to 16 weeks. These questionnaires are online so you can complete them at a time that is convenient for you. You will also need the time to attend the six therapy sessions. Therapy sessions will last up to 50 minutes. Timings of therapy sessions will be agreed between you and the therapist to ensure they suit your schedule.

Who has reviewed this study?
All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by NAME Research Ethics Committee (REC NUMBER). The research has also been approved by the Royal Holloway, University of London research ethics committee. This means that these research governing bodies believe that the research is ethical and that all risks have been minimised and that your rights as participants will be respected by the research team.

What will happen to the results of this study?
The data collected during the study will be used as a part of a Doctoral Clinical Psychology project at the Royal Holloway University of London. Research findings will be submitted as part of doctoral thesis. In addition, I will write up an article for publication in a journal, again no participant information will be identifiable. The research may be presented at conferences and written up for mainstream media. Results may be shared with Clinical Psychology Training courses and specific NHS services.

Taking part in this study
If you wish to take part in this study, please email me at alexandria.phillips1@nhs.net or let someone from your care team know and I can contact you.

Further information
This project is supervised by Dr Katie Ashcroft, Clinical Psychologist and Academic Tutor, Royal Holloway University of London and Dr Esme Banting, Senior Clinical Psychologist, Ashford and St Peter's Hospital Specialist Weight Management Service.

Although we hope it is not the case, if you have any complaints or concerns about any aspect of the way you have been approached or treated during the course of this study, please contact the lead supervisor Dr Katie Ashcroft at katie.ashcroft@rhul.ac.uk.

If you have a complaint about how this research is conducted, please contact the Patient Advice and Liaison Service (PALS) who can offer confidential advice, support and information:
PALS telephone: 01932 723553

Thank you very much for reading this information and considering taking part in this study.

Appendix B

Informed Consent Form

Informed Consent Form
Study Title: Talking therapy for body awareness and managing emotions for people living with obesity: a multiple baseline study

	Tick here:
The nature and purpose and potential benefits or risks of the study have been explained to me. I have read and understood the participant information sheet (version 1.0 dated 05.05.22) and understand what this study involves. If I asked questions, they have been answered fully to my satisfaction.	☐
I can commit for up to 16 weeks for the entirety of the study and understand the commitment needed in terms of daily and weekly questionnaires.	☐
I understand that my participation in the study is entirely voluntary and that I am free to withdraw at any time without giving a reason.	☐
I agree to the research therapist accessing my medical records to verify my health status.	☐
I agree that if I decide to withdraw from the study then the researchers can continue to use the data and information I have already given them unless I ask for this to be destroyed.	☐
I agree to the therapy sessions being recorded (please note this is optional, if you do not agree to have your therapy sessions recorded, this will not affect your ability to take part in the study).	☐
Agree to my GP being informed that I'm taking part in the study	☐
I understand that all data will be kept confidential and that no personal, identifying information will be disclosed in any reports on the project, or to any other party	☐
I understand that the researcher may contact my care team, GP or relevant authorities, if they are concerned about my safety or the safety of others.	☐
I agree to take part in the study	☐

Participant electronic signature:_____
Date:_____

Appendix C

Advertising Flyer

ROYAL HOLLOWAY UNIVERSITY OF LONDON

NHS

Ashford and St. Peter's Hospitals

NHS Foundation Trust

Research study invite

TALKING THERAPY FOR BODY AWARENESS AND MANAGING EMOTION

PEOPLE LIVING WITH OBESITY CAN FIND IT DIFFICULT TO NOTICE AND COPE WITH EMOTIONS. THIS CAN CONTRIBUTE TO DIFFICULTIES MAINTAINING A HEALTHY WEIGHT.

THIS STUDY IS LOOKING TO EVALUATE A TALKING THERAPY THAT AIMS TO IMPROVE BODY AWARENESS AND MANAGING EMOTIONS.

YOU WILL BE OFFERED SIX ONE-TO-ONE ONLINE THERAPY SESSIONS WITH A TRAINED THERAPIST AND BE ASKED TO COMPLETE SOME QUESTIONNAIRES.

You are eligible to take part if you:

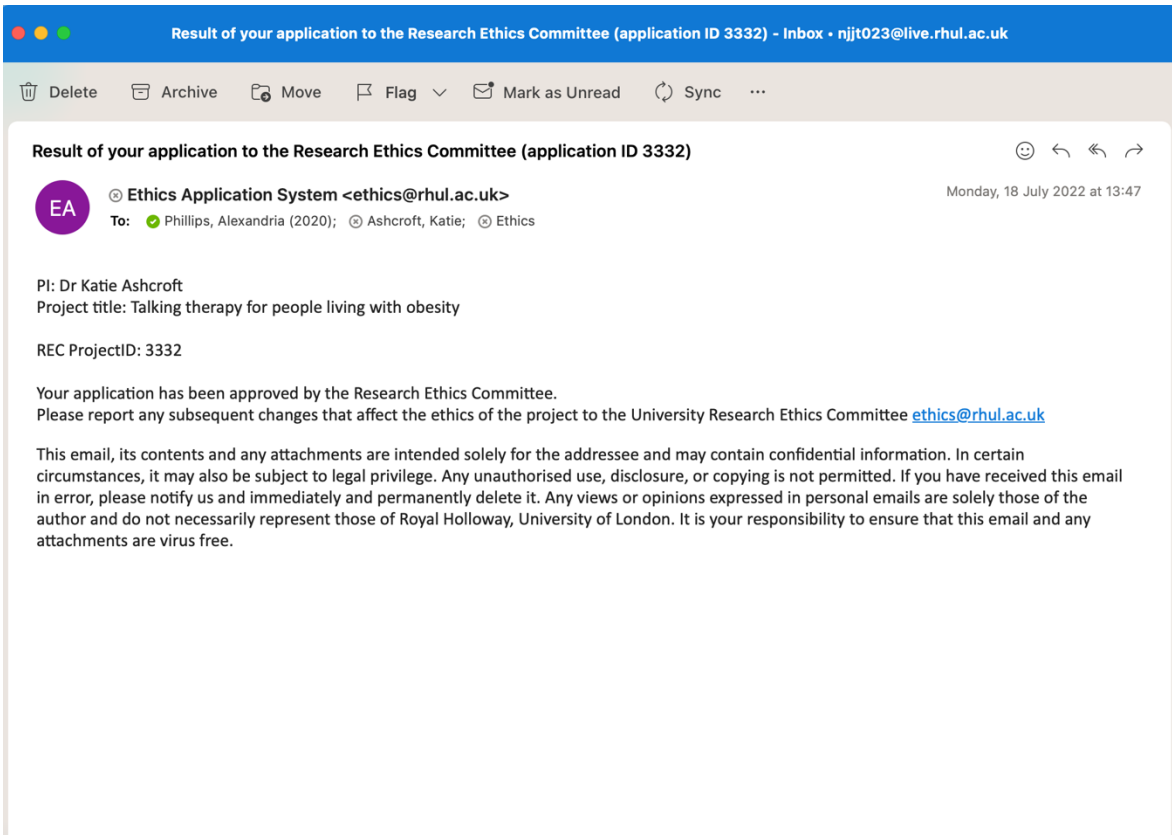
- **Are a service user with ASPH Specialist Weight Management Service**
- **Can commit for up to 16 weeks completing questionnaires every day**
- **Have internet access for online therapy sessions and completing questionnaires**

IF YOU WOULD LIKE TO FIND OUT MORE PLEASE SPEAK TO YOUR CARE TEAM OR EMAIL: ALEXANDRIA.PHILLIPS1@NHS.NET

IRAS: 308241
V1.0 26/04/2022

Appendix D

Royal Holloway University of London (RHUL) Research Committee Ethical Approval



Result of your application to the Research Ethics Committee (application ID 3332) - Inbox • njjt023@live.rhul.ac.uk

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Result of your application to the Research Ethics Committee (application ID 3332)

EA **Ethics Application System <ethics@rhul.ac.uk>**

Monday, 18 July 2022 at 13:47

To: Phillips, Alexandria (2020); Ashcroft, Katie; Ethics

PI: Dr Katie Ashcroft
Project title: Talking therapy for people living with obesity

REC ProjectID: 3332

Your application has been approved by the Research Ethics Committee.
Please report any subsequent changes that affect the ethics of the project to the University Research Ethics Committee ethics@rhul.ac.uk

This email, its contents and any attachments are intended solely for the addressee and may contain confidential information. In certain circumstances, it may also be subject to legal privilege. Any unauthorised use, disclosure, or copying is not permitted. If you have received this email in error, please notify us and immediately and permanently delete it. Any views or opinions expressed in personal emails are solely those of the author and do not necessarily represent those of Royal Holloway, University of London. It is your responsibility to ensure that this email and any attachments are virus free.

Appendix E

NHS and Health Research Authority (HRA) Ethical Approval

Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

NHS Health Research Authority

Miss Alexandria Phillips
Trainee Clinical Psychologist
Camden and Islington NHS Foundation Trust
4 Saint Pancras Way
London
London
NW1 0PEN/A

Email: approvals@hra.nhs.uk
HCRW.approvals@wales.nhs.uk

27 June 2022

Dear Miss Phillips,

HRA and Health and Care Research Wales (HCRW) Approval Letter

Study title:	**Talking therapy for body awareness and managing emotions for people living with obesity: a multiple baseline study**
IRAS project ID:	**308241**
Protocol number:	**N/A**
REC reference:	**22/NW/0178**
Sponsor	**Royal Holloway University of London**

I am pleased to confirm that **HRA and Health and Care Research Wales (HCRW) Approval** has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications received. You should not expect to receive anything further relating to this application.

Please now work with participating NHS organisations to confirm capacity and capability, in line with the instructions provided in the "Information to support study set up" section towards the end of this letter.

How should I work with participating NHS/HSC organisations in Northern Ireland and Scotland?
HRA and HCRW Approval does not apply to NHS/HSC organisations within Northern Ireland and Scotland.

If you indicated in your IRAS form that you do have participating organisations in either of these devolved administrations, the final document set and the study wide governance report

(including this letter) have been sent to the coordinating centre of each participating nation. The relevant national coordinating function/s will contact you as appropriate.

Please see IRAS Help for information on working with NHS/HSC organisations in Northern Ireland and Scotland.

How should I work with participating non-NHS organisations?
HRA and HCRW Approval does not apply to non-NHS organisations. You should work with your non-NHS organisations to obtain local agreement in accordance with their procedures.

What are my notification responsibilities during the study?

The standard conditions document "*After Ethical Review – guidance for sponsors and investigators*", issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:

- Registration of research
- Notifying amendments
- Notifying the end of the study

The HRA website also provides guidance on these topics, and is updated in the light of changes in reporting expectations or procedures.

Who should I contact for further information?
Please do not hesitate to contact me for assistance with this application. My contact details are below.

Your IRAS project ID is **308241**. Please quote this on all correspondence.

Yours sincerely,

Margaret Hutchinson
Approvals Specialist

Email: approvals@hra.nhs.uk
Copy to: *Dr John Francis*

IRAS 308241. Amendment

NI

New IRAS Dev <no-reply-iras@hra.nhs.uk>

Tuesday, 25 October 2022 at 19:25

To: PHILLIPS, Alexandria (ASHFORD AND ST PETER'S HOSPITALS NHS FOUNDATION TRUST)

IRAS Project ID: 308241
Sponsor amendment reference: 10001

Thank you for submitting your study amendment. In accordance with the outcome of your completed amendment tool, this amendment requires no further regulatory review. Please now share this amendment with your UK research sites, in accordance with the instructions in your completed amendment tool.

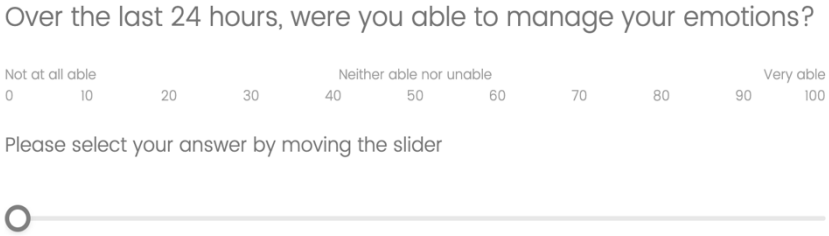
For studies with more than one UK research site, your amendment will now be automatically shared with the R&D offices of any NHS/HSC research sites in Scotland and Northern Ireland, but you should share the amendment by email directly with those Research team/s.

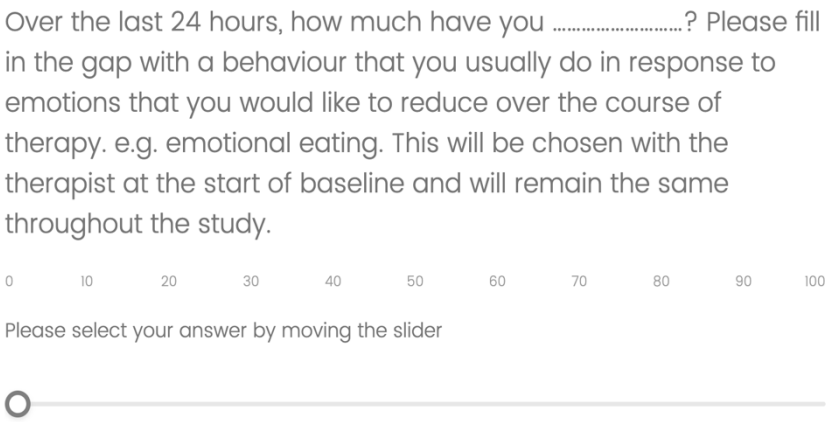
For all NHS research sites in England and Wales, please now share this amendment by email directly with those sites, including both the R&D offices and research teams.

Do not reply to this email as this is an unmonitored address and replies to this email cannot be responded to or read.

Appendix F

Visual Analogue Scales (VAS)





Appendix G

The Adverse Childhood Experience (ACE) Questionnaire

Adverse Childhood Experience (ACE) Questionnaire

Name: _____ Date: _____

This Questionnaire will be asking you some questions about events that happened during your childhood; specifically the first 18 years of your life. The information you provide by answering these questions will allow us to better understand problems that may have occurred early in your life and allow us to explore how those problems may be impacting the challenges you are experiencing today. This can be very helpful in the success of your treatment.

While you were growing up, during your first 18 years of life:

1. Did a parent or other adult in the household often:

   Swear at you, insult you, put you down, or humiliate you?

   Or

   Act in a way that made you afraid that you might be physically hurt?

   ☐ Yes ☐ No If Yes, enter 1 _____

2. Did a parent or other adult in the household often:

   Push, grab, slap, or throw something at you?

   Or

   Ever hit you so hard that you had marks or were injured?

   ☐ Yes ☐ No If Yes, enter 1 _____

3. Did an adult or person at least 5 years older than you ever:

   Touch or fondle you or have you touch their body in a sexual way?

   Or

   Attempt or actually have oral, anal, or vaginal intercourse with you?

   ☐ Yes ☐ No If Yes, enter 1 _____

4. Did you often feel that:

   No one in your family loved you or thought you were important or special?

   Or

Adverse Childhood Experience (ACE) Questionnaire

Your family didn't look out for each other, feel close to each other, or support each other?

☐ Yes ☐ No If Yes, enter 1 _____

5. Did you <u>often</u> feel that:

   You didn't have enough to eat, had to wear dirty clothes, and had no one to protect you?

   Or

   Your parents were too drunk or high to take care of you or take you to the doctor if you needed it?

   ☐ Yes ☐ No If Yes, enter 1 _____

6. Were your parents <u>ever</u> separated or divorced?

   ☐ Yes ☐ No If Yes, enter 1 _____

7. Were any of your parents or other adult caregivers:

   <u>Often</u> pushed, grabbed, slapped, or had something thrown at them?

   Or

   <u>Sometimes or often</u> kicked, bitten, hit with a fist, or hit with something hard?

   Or

   <u>Ever</u> repeatedly hit over at least a few minutes or threatened with a gun or knife?

   ☐ Yes ☐ No If Yes, enter 1 _____

8. Did you live with anyone who was a problem drinker or alcoholic, or who used street drugs?

   ☐ Yes ☐ No If Yes, enter 1 _____

9. Was a household member depressed or mentally ill, or did a household member attempt suicide?

   ☐ Yes ☐ No If Yes, enter 1 _____

10. Did a household member go to prison?

    ☐ Yes ☐ No If Yes, enter 1 _____

ACE SCORE (Total "Yes" Answers): _____

Appendix H

Difficulties in Emotion Regulation Scale (DERS)

Please indicate how often the following statements apply to you **in the last week** by selecting the appropriate number from the scale below.

1	2	3	4	5
almost never (0-10%)	sometimes (11-35%)	about half the time (36-65%)	most of the time (66-90%)	almost always (91-100%)

_____ 1) I am clear about my feelings.
_____ 2) I pay attention to how I feel.
_____ 3) I experience my emotions as overwhelming and out of control.
_____ 4) I have no idea how I am feeling.
_____ 5) I have difficulty making sense out of my feelings.
_____ 6) I am attentive to my feelings.
_____ 7) I know exactly how I am feeling.
_____ 8) I care about what I am feeling.
_____ 9) I am confused about how I feel.
_____ 10) When I'm upset, I acknowledge my emotions.
_____ 11) When I'm upset, I become angry with myself for feeling that way.
_____ 12) When I'm upset, I become embarrassed for feeling that way.
_____ 13) When I'm upset, I have difficulty getting work done.
_____ 14) When I'm upset, I become out of control.
_____ 15) When I'm upset, I believe that I will remain that way for a long time.
_____ 16) When I'm upset, I believe that I will end up feeling very depressed.
_____ 17) When I'm upset, I believe that my feelings are valid and important.
_____ 18) When I'm upset, I have difficulty focusing on other things.
_____ 19) When I'm upset, I feel out of control.
_____ 20) When I'm upset, I can still get things done.
_____ 21) When I'm upset, I feel ashamed at myself for feeling that way.
_____ 22) When I'm upset, I know that I can find a way to eventually feel better.
_____ 23) When I'm upset, I feel like I am weak.
_____ 24) When I'm upset, I feel like I can remain in control of my behaviors.
_____ 25) When I'm upset, I feel guilty for feeling that way.
_____ 26) When I'm upset, I have difficulty concentrating.
_____ 27) When I'm upset, I have difficulty controlling my behaviors.
_____ 28) When I'm upset, I believe there is nothing I can do to make myself feel better.
_____ 29) When I'm upset, I become irritated at myself for feeling that way.
_____ 30) When I'm upset, I start to feel very bad about myself.
_____ 31) When I'm upset, I believe that wallowing in it is all I can do.
_____ 32) When I'm upset, I lose control over my behavior.
_____ 33) When I'm upset, I have difficulty thinking about anything else.
_____ 34) When I'm upset I take time to figure out what I'm really feeling.
_____ 35) When I'm upset, it takes me a long time to feel better.
_____ 36) When I'm upset, my emotions feel overwhelming.

Reverse-scored items (place a subtraction sign in front of them) are numbered 1, 2, 6, 7, 8, 10, 17, 20, 22, 24 and 34.
Calculate total score by adding everything up. Higher scores suggest greater problems with emotion regulation.
SUBSCALE SCORING:** The measure yields a total score (SUM) as well as scores on six sub-scales:
1. Nonacceptance of emotional responses (NONACCEPT): 11, 12, 21, 23, 25, 29
2. Difficulty engaging in Goal-directed behavior (GOALS): 13, 18, 20R, 26, 33
3. Impulse control difficulties (IMPULSE): 3, 14, 19, 24R, 27, 32
4. Lack of emotional awareness (AWARENESS): 2R, 6R, 8R, 10R, 17R, 34R
5. Limited access to emotion regulation strategies (STRATEGIES): 15, 16, 22R, 28, 30, 31, 35, 36
6. Lack of emotional clarity (CLARITY): 1R, 4, 5, 7R, 9

Total score: sum of all subscales
**"R" indicates reverse scored item

REFERENCE:

Gratz, K. L. & Roemer, L. (2004). Multidimensional assessment of emotion regulation and dysregulation: Development, factor structure, and initial validation of the Difficulties in Emotion Regulation Scale. *Journal of Psychopathology and Behavioral Assessment, 26,* 41-54.

Appendix I

Multidimensional Assessment of Interoceptive Awareness (MAIA-2)

Below you will find a list of statements. Please indicate how often each statement applies to you **in the last week.**

.	Circle one number on each line					
	Never					Always
1. When I am tense I notice where the tension is located in my body.	0	1	2	3	4	5
2. I notice when I am uncomfortable in my body.	0	1	2	3	4	5
3. I notice where in my body I am comfortable.	0	1	2	3	4	5
4. I notice changes in my breathing, such as whether it slows down or speeds up.	0	1	2	3	4	5
5. I ignore physical tension or discomfort until they become more severe.	0	1	2	3	4	5
6. I distract myself from sensations of discomfort.	0	1	2	3	4	5
7. When I feel pain or discomfort, I try to power through it.	0	1	2	3	4	5
8. I try to ignore pain	0	1	2	3	4	5
9. I push feelings of discomfort away by focusing on something	0	1	2	3	4	5
10. When I feel unpleasant body sensations, I occupy myself with something else so I don't have to feel them.	0	1	2	3	4	5
11. When I feel physical pain, I become upset.	0	1	2	3	4	5
12. I start to worry that something is wrong if I feel any discomfort.	0	1	2	3	4	5
13. I can notice an unpleasant body sensation without worrying about it.	0	1	2	3	4	5
14. I can stay calm and not worry when I have feelings of discomfort or pain.	0	1	2	3	4	5
15. When I am in discomfort or pain I can't get it out of my mind	0	1	2	3	4	5
16. I can pay attention to my breath without being distracted by things happening around me.	0	1	2	3	4	5
17. I can maintain awareness of my inner bodily sensations even when there is a lot going on around me.	0	1	2	3	4	5
18. When I am in conversation with someone, I can pay attention to my posture.	0	1	2	3	4	5

How often does each statement apply to you generally in daily life? Circle one number on each line

	Never					Always
19. I can return awareness to my body if I am distracted.	0	1	2	3	4	5
20. I can refocus my attention from thinking to sensing my body.	0	1	2	3	4	5
21. I can maintain awareness of my whole body even when a part of me is in pain or discomfort.	0	1	2	3	4	5
22. I am able to consciously focus on my body as a whole.	0	1	2	3	4	5
23. I notice how my body changes when I am angry.	0	1	2	3	4	5
24. When something is wrong in my life I can feel it in my body.	0	1	2	3	4	5
25. I notice that my body feels different after a peaceful experience.	0	1	2	3	4	5
26. I notice that my breathing becomes free and easy when I feel comfortable.	0	1	2	3	4	5
27. I notice how my body changes when I feel happy / joyful.	0	1	2	3	4	5
28. When I feel overwhelmed I can find a calm place inside.	0	1	2	3	4	5
29. When I bring awareness to my body I feel a sense of calm.	0	1	2	3	4	5
30. I can use my breath to reduce tension.	0	1	2	3	4	5
31. When I am caught up in thoughts, I can calm my mind by focusing on my body/breathing.	0	1	2	3	4	5
32. I listen for information from my body about my emotional state.	0	1	2	3	4	5
33. When I am upset, I take time to explore how my body feels.	0	1	2	3	4	5
34. I listen to my body to inform me about what to do.	0	1	2	3	4	5
35. I am at home in my body.	0	1	2	3	4	5
36. I feel my body is a safe place.	0	1	2	3	4	5
37. I trust my body sensations.	0	1	2	3	4	5

Appendix J

15-item Five-Factor Mindfulness Questionnaire (FFMQ-15)

Please use the 1 (never or very rarely true) to 5 (very often or always true) scale provided to indicate how true the below statements are of you. Circle the number in the box to the right of each statement which represents your own opinion of what is generally true for you **in the last week**.

For example, if you think that a statement is often true of you, circle '4' and if you think a statement is sometimes true of you, circle '3'.

	Never or very rarely true	Rarely true	Some -times true	Often true	Very often or always true
1. When I take a shower or a bath, I stay alert to the sensations of water on my body.	1	2	3	4	5
2. I'm good at finding words to describe my feelings.	1	2	3	4	5
3. I don't pay attention to what I'm doing because I'm daydreaming, worrying, or otherwise distracted.	1	2	3	4	5
4. I believe some of my thoughts are abnormal or bad and I shouldn't think that way.	1	2	3	4	5
5. When I have distressing thoughts or images, I "step back" and am aware of the thought or image without getting taken over by it.	1	2	3	4	5
6. I notice how foods and drinks affect my thoughts, bodily sensations, and emotions.	1	2	3	4	5
7. I have trouble thinking of the right words to express how I feel about things.	1	2	3	4	5
8. I do jobs or tasks automatically without being aware of what I'm doing.	1	2	3	4	5
9. I think some of my emotions are bad or inappropriate and I shouldn't feel them.	1	2	3	4	5
10. When I have distressing thoughts or images I am able just to notice them without reacting.	1	2	3	4	5
11. I pay attention to sensations, such as the wind in my hair or sun on my face.	1	2	3	4	5
12. Even when I'm feeling terribly upset I can find a way to put it into words.	1	2	3	4	5
13. I find myself doing things without paying attention.	1	2	3	4	5
14. I tell myself I shouldn't be feeling the way I'm feeling.	1	2	3	4	5
15. When I have distressing thoughts or images I just notice them and let them go.	1	2	3	4	5

Appendix K

The Client Feedback form

This questionnaire asks you about how acceptable you found polyvagal informed therapy. These questions relate specifically to the six sessions of talking therapy you received and not to the research study as a whole. Please read the following questions and statements and indicate your answer by selecting one of the options below each question. Please answer these questions as honestly as possible as your feedback will help us to make changes and improve how polyvagal informed therapy may be delivered in the future.

1. Did you like or dislike polyvagal informed therapy?

Strongly dislike	Dislike	No opinion	Like	Strongly like
1	**2**	**3**	**4**	**5**

2. How much effort did it take to engage with polyvagal informed therapy?

No effort at all	A little effort	No opinion	A lot of effort	Huge effort
1	**2**	**3**	**4**	**5**

3. Polyvagal informed therapy has improved my ability to regulate my body and emotions

Strongly disagree	Disagree	No opinion	Agree	Strongly agree
1	**2**	**3**	**4**	**5**

4. It is clear to me how polyvagal informed therapy will help me be aware of and manage my body and emotions

Strongly disagree	Disagree	No opinion	Agree	Strongly agree
1	**2**	**3**	**4**	**5**

5. How confident did you feel about engaging with polyvagal informed therapy?

Very unconfident	Unconfident	No opinion	Confident	Very confident
1	**2**	**3**	**4**	**5**

6. Engaging in polyvagal informed therapy interfered with my priorities

Strongly disagree	Disagree	No opinion	Agree	Strongly agree
1	**2**	**3**	**4**	**5**

7. How acceptable was polyvagal informed therapy to you?

Completely unacceptable	Unacceptable	No opinion	Acceptable	Completely acceptable
1	**2**	**3**	**4**	**5**

8. Can you tell us, in your own words, what you found helpful and less helpful in relation to the intervention?

9. Can you tell us, in your own words, what difference, if any, the intervention has had on your day-to-day life?

Appendix L

PVTT Therapy Manual

Polyvagal Informed Therapy for People with Bigger Bodies

Dr Katie Ashcroft
Lecturer, Royal Holloway University of London
10th May 2022

Acknowledgments

This manual draws upon the work of Steven Porges' Polyvagal theory and Deb Dana's Polyvagal Theory in Therapy. Thanks go to my colleagues Dr Alex Fowke, Dr Rebecca Lee and Njoki Wamae for their support with implementing PVT in my clinical practice. This manual also draws heavily upon the work of Marsha Linehan and Thomas R Lynch and their respective skills training manuals. Many of the skills in this manual can also be found in publications by these authors. I must also thank the clients I have worked with in the past few years for helping me to refine my practice. Special thanks go to Peter for designing and sharing the ANS tracker document. Thank you to my assistant Cristina Campbell-Hewson for her support with preparation of this document. Finally thanks go to Dr Alex Fowke for his review of the manual and Dr Esme Banting, who also reviewed this manual, commenting on its appropriateness for use with people with bigger bodies.

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Consolidation and Relapse Prevention
Appendix 1 – ANS Diagram
Appendix 2 – ANS Tracker

Key Principles

There are three organising principles at the centre of Polyvagal Theory (PVT). First is the Autonomic Nervous System (ANS) hierarchy – the ANS responds to sensations in the body and environment through 3 pathways of response. These work in evolutionary order, from oldest to newest.

1. The Dorsal Vagus (DV) – the immobilisation system.
2. The Sympathetic Nervous System (SNS) – the mobilisation system.
3. The Ventral Vagus (VV) – the social engagement system.

Secondly, there is a focus on neuroception. This is the way the ANS responds to cues from the body, the world and connection to others. It is detection without awareness as the body has the capacity to process this information so quickly, prior to it being conscious. This point is particularly pertinent as it explains how, in some instances, we can shift into threat/mobilisation or immobilisation and not understand what has triggered the change. Understanding this is often liberating for clients and can assist in the reduction of judgement and self-criticism. For example, individuals no longer label themselves as over-emotional, unbalanced or out of control.

Thirdly, the biological imperative of coregulation. This need must be met to sustain life. It is most simply demonstrated in the infant's need for a responsive caregiver and the distress and attempts to obtain a reaction when one is withheld. However, we all experience discomfort when we do not receive the socially expected responses from those we are trying to engage with. It is through reciprocal regulation of the ANS state that we feel safe to move into connection and create all manner of trusting relationships.

Additionally, there are a further five principles that sit at the core of the intervention in this manual.

1. **Respect for the ANS** – shifts down the ANS ladder are functional, our physiology is doing its best to give us what we need. The problem is not that we move into immobilisation or mobilisation, rather it is that we may not be aware of where we are physiologically and/or know how to get back to safe and connected (VV).
2. **Collaborative enquiry between therapist and client** - curiosity, monitoring and experimentation allow greater understanding and the development of effective strategies to manage the physiological state.
3. **Each client is unique** – the past experiences, relationship with the body, and pattern of emotional coping will be different for everyone. This is also the case when it comes to the strategies to manage SNS and DV.
4. **The secret is practice** – the success of the intervention is largely dependent on an individual's ability to monitor their ANS frequently and try a range of coping strategies. Thus, troubleshooting around homework not being completed and/or documented is essential.
5. **Maximising learning** – we are all capable of doing something new and not learning from it. Consequently, the therapist's job is to provide a space in which all of the results of the curiosity and experimentation are reviewed, and the client is given space to reflect on what they learn from this. At first the therapist may need to scaffold the

client, drawing pieces of information together and asking the question or, if necessary, making a suggestion themselves. As sessions go on, less scaffolding may be needed and clients will get into the rhythm of articulating what they have learnt, and, consequently what they are going to continue doing and/or try differently. To support this, it is recommended that clients take notes in sessions on their learning points, as well as homework tasks. It is also vital that clients retain weekly ANS tracker documents so that they can review data across different weeks.

The above means that all data is grist for the therapy mill, experiences of SNS and DV are opportunities to be learnt from; either what increased vulnerability, triggered movement down the ANS ladder or how the physiological state can be addressed. Success will not be measured in never experiencing SNS or DV, rather in growing resilience i.e., the ability to move out of them, mostly at will and more swiftly than previously.

The intervention requires detailed examination of shifts up and down the ladder. It may take a while for therapist and client to find the right balance. Too little detail is likely to lead to short sessions with homework that feels a bit arbitrary. Clients who have previously worked with the cognitive model and/or find it easier to focus on their thinking, may take a while to transition to a more physical emphasis. This is all part of the process of reorientating to the body and can be supported by therapist questions and summaries.

Overview of the Intervention

The outline of sessions are as follows:

1. Introduction to polyvagal theory
2. Application of polyvagal theory to client's difficulties
3. Mapping on the polyvagal ladder
4. Exercises to regulate up the ladder
5. Practicing exercises and mapping on the ladder
6. Summarising and therapy blueprint

Introducing the Client to the Intervention

As with any psychological intervention, it is important to engage the client, establishing a good therapeutic alliance. Thus, it is suggested that the therapist begins with assessing the client's current experience of anxiety, anger, sadness, and detachment, and how they cope with each of these. The client has the opportunity to be heard and the therapist can hone in on the client's current phraseology, seeking clarification where necessary. It is also the opportunity to validate difficulties and give a different conceptualisation to coping behaviour. Like Dialectical Behaviour Therapy, PVTBB takes the perspective that clients are doing the best they can and so they need to do something different. It is completely understandable that eating soothes as sucking, chewing, and swallowing are associated with safety. Check with client at precisely what point they start and stop to feel better when eating. You may find it is immediate but stops as soon as the chewing, swallowing, or sucking stops. This is an excellent example of how the client is doing their best to activate the PNS and a nice point to explain they can learn how to do it in different ways.

Psychoeducation on the Autonomic Nervous System

This section supports the practitioner to educate the client on the ANS with a mixture of teaching and discussion points. The idea is to outline the three systems in an appropriate level of detail for each client, allowing them to reflect on their experiences of each state. We particularly want to emphasise the normality and functionality of movement up and down the ANS ladder in service of the client taking a respectful, curious, and accepting stance of shifts. By doing this, we can create interest in bodily states, acknowledgement of changes and, as a result, increase the likelihood of the employment of effective coping strategies.

It is suggested that the therapist starts with the SNS and PNS, getting the client to draw two circles and putting the information in them, along with what they notice in their bodies. A bidirectional arrow can then be drawn between the two circles and labelled vagus nerve. This pictorial representation of the systems allows the therapist to emphasise that we need the correct amount of each dependent on what we are doing, that they are the accelerator and break on a car. Asking the client to draw this out allows them to process the information. The ANS ladder diagram can then be introduced when DV and coregulation are discussed. The intention is for the client to be clear on a couple of concepts before introducing other new ones.

The Sympathetic Nervous System

Teaching Point: The sympathetic nervous system is our fight or flight response. The very ancient area of the brain that is a part of this system is called the basal ganglia, sometimes referred to as the crocodile brain. It takes a small amount of information and jumps to the conclusion that there is threat. In doing so, it triggers the body to pump out the hormone adrenaline. This ensures that the blood supply is taken away from the digestive system and sent to the arms and legs, so that we can stay, fight and defend ourselves, or run away.

It is this mobilising system that takes over when we feel anxious and experience all the associated bodily sensations that go with this, including increased heart rate, nausea, blurred vision, having sweaty hands and feeling shaky. It is also this system that is in charge when we are feeling angry, with the associated symptoms of rapid breathing, tension, clenched fists etc.

Discussion Point: What physiological changes do you notice in your body when you are anxious? And when you are angry?

Teaching Point: Given that our crocodile brain is running the show, we cannot concentrate, be creative or think our way out of feeling anxious or angry. This is completely understandable given that we don't have access to the part of the brain that allows us to do this - the frontal cortex. There is no survival value in the frontal cortex being able to challenge the assumption of threat that the crocodile brain has made. When we are crossing the road and we hear a speeding car, we need to be mobilised to get out of the way quickly. We do not need to hang around assessing the speed of the car, the weather conditions, and the likely braking distance.

Discussion point: Have you experienced strong anxiety or anger when you have found it difficult to think or concentrate?

The Parasympathetic Nervous System

Teaching Point: The parasympathetic nervous system is the self-soothes and affiliation drive otherwise known as the social engagement system. The part of the brain associated with this drive is the frontal cortex just behind our foreheads, which makes our forehead stick out, in comparison to our monkey and ape relatives. The frontal cortex is unique to humans, and is the centre for executive functioning and creativity, i.e. self-awareness, planning activities and starting, monitoring, and completing activities are located in this part of the brain.

The hormone associated with this drive is oxytocin, sometimes mistakenly called the love drug. Oxytocin is created when we are holding hands with a partner or playing with our child, but also when we are trying to defend a loved one who we perceive to be under threat. Oxytocin is a powerful painkiller, decreasing the brain's response to pain (Kessner et al., 2013; Zunhammer et al., 2016). There is also evidence that oxytocin improves our social performance, such as in tasks where we must infer someone else's internal state (Domes et al., 2007). It is the PNS that is activated when other people are responsive and warm towards us and that make us feel at ease.

We are the most prosocial species on the planet. This, along with our creativity, has contributed to our survival and our dominance. From birth, we are tuned in to focus on human faces more than any other stimuli. You can even rearrange the features of a human face somewhat and a new-born baby will still spend more time looking at it compared to other stimuli. Being liked and accepted by other people in our tribe used to be a matter of life or death. While our environment has changed, and we are no longer required to be part of a group to survive, our hardwiring hasn't changed and picking up any slight signal about not being liked or accepted can trigger a powerful response in us. It's possible to survive in today's world without connection with others, but to thrive, we need coregulation. It would also be an oversimplification to say we no longer rely on other people for survival. We are dependent on farmers, shop and factory workers and a wide range of seen and unseen others.

Discussion Point: Can you think of an example when you have felt uneasy because of how someone was responding to you? Examples of not being listened to or incongruous facial expressions work well here. See if you can discuss a few different examples with the client and make it about the non-verbal communication, and how they felt emotionally and physically.

Ventral Vagus Nerve

Teaching Point: The vagus nerve is one of the 12 cranial nerves and has two branches. The first branch, the myelinated or fast branch, comes out of the brain and runs through our jaw into our heart, lungs, and stomach. It then wanders back up through the throat (pharynx and larynx), through our striated facial muscles and connects with the ears and the eyes.

The fast ventral vagus (VV) can be felt when it turns off. Those moments when we realise that we have forgotten something or hear a noise that makes us jump and we feel that lurch in the stomach or skip of the heart. This feeling is the vagal brakes being turned off, thereby shrinking the PNS and enlarging the SNS, driving the fight or flight response.

Given that we can't think our way out of threat as the crocodile brain isn't capable of that, the first thing we need to understand about managing the SNS is that we need to use our bodies

to get us back into PNS (safe and connected). An effective way of turning on the VV brakes is six breaths per minute (6BPM). For a long time, therapists have been teaching clients with anxiety to breathe slowly and deeply. Now, we understand how this works. Steven Porges has spent the last 40 years researching the vagus nerve and has understood that breathing at a rate of six breaths per minute or less turns on the vagal brakes, thereby taking the foot off the accelerator of the SNS.

Exercise: When practising this in session with the client, get them to place one hand on their chest (just under their collarbone) and one hand either on the stomach or on their waist. Breathing deeply is as important as breathing slowly, as doing so moves the diaphragm and is a safety signal to the brain. Encourage clients to think about the movement of the stomach and the lower ribs three-dimensionally, in whichever way allows them to enhance and connect with movement in the lower body. As well as how the client visualises a deep breath, you can also ask them to move the lower hand around to find where they can connect with most movement. Don't aim for a particular number of breaths per minute, rather, encourage the client to slow their breathing down and deepen their breathing. The inbreath should start from the waist, prompting the lower hand to move before the upper hand. On the outbreath, the upper hand should move first and clients can continue to breathe out after they believe they have finished, causing a contraction of the stomach muscles. Get the client to notice any thoughts they may have about doing this, encouraging pauses after the inhalation and exhalation, and slowing it down a little bit further. Clients often stop an inhalation or exhalation because they are bored of breathing in or out, so name this, and encourage continued inhalation and exhalation. It is important to understand that when we breathe in, it is SNS activation and when we breathe out, it is PNS activation. Consequently, we want a longer out-breath than in-breath to maximise PNS activation. Having done this exercise for a few minutes, discuss how they found it, noting the impact on how they felt physically and emotionally. Review their cognitions. Clients sometimes get concerned about a lack of oxygen; normalise these concerns and remind them that the body is capable of breathing as needed when we are asleep without our conscious control of it.

Homework (1): Agree with the client a daily practice. Many clients are unable to breathe at a rate of six breaths a minute straight away, so it is worth starting with as slow as they feel able, doing so daily for at least two or three minutes each time and preferably multiple times a day, and then decreasing the speed of their breathing by one breath per minute each week. There are many apps that can help with this practice, just ensure the client chooses one they feel comfortable with and that gives a longer outbreath than inbreath. Do check if the client believes anything will get in the way of doing homework and problem solve this with them if necessary.

Homework Review: Ascertain the frequency and duration of practice and what emotional shifts the client noticed. This item needs to stay on the homework review list for each session as the client is supported to start to use this skill in a wider range of situations, without the use of apps or clocks and while engaged in a variety of activities.

Homework (2)**:** A video that may help the client to better understand the structure and function of the ANS: https://www.youtube.com/watch?v=71pCilo8k4M.
Homework Review: Does the client have any questions about the video or what was covered in the red (SNS) and green (SES) last session?
Dorsal Vagus Nerve

Teaching Point: Use the ANS ladder diagram (Appendix 1) to illustrate the following discussion on DV, self and coregulation. The slow or nonmyelinated branch of the vagus nerve, called the dorsal vagus (DV), connects with the large intestine. This second branch carries a huge amount of information between the gut and the brain predominantly in that direction and is responsible for the brain receiving information to say that we are at ease or under extreme threat. The bottom of the ladder is a place of immobilisation, it is a protective state of numb, disconnected and, at its most extreme, collapse or freezing. Our experience here is one of feeling alone, too tired, or too heavy to move or think properly. This is the place we are likely to experience dissociation (either feeling removed from the body or being on autopilot).
This is why the large intestine is now being referred to as the second brain.
Discussion Point: Let's have a think about some of your experiences and see if they might be located in this dorsal vagal section at the bottom of the ladder. Looking at what is described, have you experienced any of these?
Coregulation

Teaching Point: The biological imperative of coregulation must be met to sustain life. It is most simply demonstrated in the infant's need for a responsive caregiver and the distress and attempts to obtain a reaction when one is withheld. However, we all experience discomfort when we do not receive the socially expected responses from those we are trying to engage with. It is through reciprocal regulation of the ANS state that we feel safe to move into connection and create all manner of trusting relationships. Coregulation is our ability to be soothed by other people. This is most obvious when we think about how adults are with small children or animals. We intentionally use lots of intonation and are very smiley, nonthreatening, and soothing. There is a reciprocity and turn taking, which keeps us in PNS. When this is removed, we feel very uncomfortable, distressed, or threatened. The Mother's Still Face experiment is an excellent example of this. As we watch this short clip, remember that your ANS is just like the baby's.

https://www.youtube.com/watch?v=apzXGEbZht0

This coregulation, or feeling the absence of it, is equally powerful but more subtle between adults. If we are supported by coregulating relationships, we are more resilient. If we have relationships that are dominated by misattunement, we will spend much more time in SNS and DV. The pandemic has highlighted the importance of the presence and response of others in maintaining our mental health and ability to function. Lack of other people in our work environments during lockdown is one good example of how the proximity of individuals who we know to be supportive if required allows us to be calmer and function better.

Discussion Point: Reflect with the client on instances when they are aware of other people putting them at ease versus examples when they have felt uneasy with another who has been unresponsive, whether that is looking at their phone during a conversation or being blank faced in response to what the client says. Get them to articulate how it feels physically and emotionally in such instances. Note – some clients find warm attentive others too much, it is almost as though the warmth is experienced as unpleasantly hot. Such clients will manage this by controlling what they receive from the other person, spending limited time with them, listening while looking away, preferring to engage with the other when walking rather than sitting etc.

Teaching Point: The final part of the ANS ladder diagram is the arrow referring to self-regulation. There are times when we will have access to responsive others, and we will be able to use coregulation. At other times, we will need to manage our physiological state without this input. This is the focus of the rest of the work we are going to do in these sessions.

Homework: Have a look at the ANS ladder between now and the next session. Think about the description for DV and see if you can put into words your experience of DV for discussion in our next session.

Homework Review: go through the client's phraseology in detail, preferably with several examples. This will allow a clear definition of their experience of DV.

Teaching point: Introducing the ANS tracker (see Appendix 2)

This Excel document allows the client to colour code using A1 A2 A3 for green, B1 B2 B3 for red and C1 C2 C3 for DV. The client can also enter information as to what was happening/contributing to where they were on the ANS ladder. This is a suggested way of tracking the ANS and clients are very welcome to document their states, triggers and coping in another way they might find useful. It is only through detailed tracking and having multiple data points every day that therapist and client increase their understanding of physical state and the contributing factors to it. Setting an alarm that goes off intermittently throughout the day (at least 6 times) is an excellent way to ensure tracking is completed. Anecdotal reports suggest that clients can be unaware of their emotional state until their alarm goes off and they are prompted to reflect and complete the tracking document.

Managing the ANS Response

Prevention strategies

There are a range of behaviours, most notably summarised in Linehan's DBT skills training manual, that reduce our vulnerability to physiological stress. We can view this as the baseline or background physiology, and, if it is more firmly in VV then it will take more to push us down the ladder. A useful analogy is a pot of water on the hob; if it is already simmering, it doesn't take long when the heat is turned up for it to boil over. If on the other hand, the water is only tepid, it is going to take longer and/or a larger trigger for it to boil over. Consequently, this section covers sleep, environmental factors, social contact, treating physical illness, avoiding mood altering drugs, as well as hunger and thirst. It may be that some issues, including physical health conditions, cannot easily be addressed whereas others, such as poor sleep hygiene, are open to substantial change across the duration of the intervention. For all areas in prevention the therapist needs to hold the concept of the zone of proximal development (ZOPD) in mind. That is, what the individual can achieve with the aid of a supportive other in comparison to working alone. There may be a large ZOPD for some issues and none for others. Therapists should avoid compromising the therapeutic alliance by pushing for change in an area the client has no interest in changing.

- **Sleep**

If we haven't slept well or have been deprived of sleep, we are much more likely to have the SNS activated (Tobaldini et al, 2017). Thus, one way to reduce vulnerability to SNS is to ensure that clients are getting the right amount of good quality sleep (Jerath et al., 2019). It is worth being thorough when discussing this, covering all the areas listed and negotiating changes in several if necessary. Please use the link below to access an NHS document with comprehensive lists around sleep hygiene and bedtime routine.
https://web.ntw.nhs.uk/selfhelp/leaflets/Sleeping%20Problems.pdf

Clients may need support to think of alternative activities before bed if necessary, agree on what they are willing to change, and then assess the results. If less than desirable, an experiment could be conducted for a week or two on issues they are unsure about changing. Data can be reviewed, and the client can decide if the cost is worth the benefit. When going through this section, don't assume that clients sleep in a bed and/or have complete control over their environments.

- **Social Contact**

Think about good social contact of the coregulating kind on several different levels. At the top of the pyramid is the contact from a supportive romantic relationship and the associated touch and soothing. Stepping down one level, for those who have young children, there are the times when there is play or shared activity that is full of reciprocity and/or soothing; bath time or relaxing bedtime routines would be good examples. Thirdly, there is contact with friends who listen, take turns, show concern, and who we can both laugh with and express sadness to. There are then the brief interactions and chats with acquaintances/colleagues. Finally, at the base of the pyramid, there are the small interactions, the glance, nod or smile we might share with others in our vicinity.

Each of the above is coregulating and the pandemic has demonstrated the importance of even the tiny interactions. Some clients will be aware of the impact of contact with other people while others may need to experiment with the type, amount, and frequency of human contact to understand the impact it has upon them. The value of the micro-interaction should not be underestimated. Individuals who have noticed a substantial difference in their work performance, if doing so from home in the pandemic, may not attribute the change to lack of coregulation. However, depending on their current working circumstances, it may be a variable they can experiment with.

- **Environment**

Putting the presence of other people to one side, noise, or the lack of it, appears to contribute to shifts down the ANS ladder. Preferences are very personal and are likely to vary depending on task. Environments that are too quiet can be problematic. Given the ability of nature to stimulate the VV, clients may wish to experiment with background noise from the natural world. The BBC Sounds archive is a rich source of noises. Additionally, holding the importance of prosody in the human voice in mind, music, or radio can be trialled. Clients may wish to experiment with soothing and upbeat music, determining which they need when. Music in languages unknown to the listener can be useful if clients have a tendency to get lost in the meaning of lyrics. Beware of TV or radio programs that are all about disagreement, discord, and anger. These are not the material required to move back up the ANS ladder.

- **Food/Hunger/Thirst**

Some of us are aware that we can be irritable when dehydrated or hungry, but this is news for others. Thus, considering the role of dehydration and low blood sugar levels is necessary. Again, we are aiming to normalise, for the client to respect their physiology and work in harmony with it. We have reached a stage where most of us are so focused on what we are thinking, reading/watching, and doing that we expect our bodies to keep on functioning even though we ignore them. The overarching principle with all areas in prevention is to see if we can reduce our vulnerability to movement down the ladder by giving the body the consideration it deserves.
Check in with clients about frequency of eating, if there are very long gaps could clients be very hungry and therefore entering SNS? The only way to answer this is to look at the detail on the tracker, experiment with frequency of eating and monitor the results.

- **Avoiding Mood Altering Drugs**

The list of mood-altering drugs is longer than one might think. There are illicit/recreational drugs as well as over-the-counter medications that can be misused and abused. Equally, there are those which are viewed as a normal part of everyday life, such as caffeine, alcohol, and tobacco. Be open minded about what people may use, phrasing your questions in terms of "how often do you use?" rather than "do you use?". Also, try to be clear about how much is consumed, pinning alcohol down to number of units, the number and strength of codeine tablets, how many cups of what kind of coffee? Hold in mind the physiological and psychological – "I deserve this glass of wine; it is how I unwind after a busy day". Again the therapist needs to make a choice, they may easily see a pattern but may decide to let the client see the theme across the days or weeks of ANS tracking.

- **Treating Physical Illness**

Work in this area may range from encouraging a client to seek a GP appointment to discuss HRT, blood tests for anaemia or thyroid problems, basic pain management or screening for something they are worried about. Or at the other end of the spectrum, asking the client to give their honest view about how compliant they are with managing a long-term condition like diabetes or asthma. It is not for the therapist to be the expert on any diagnosis, rather to support the client to obtain and/or engage in effective care. If individuals are non-compliant with a treatment regimen the therapist can seek to understand what impact the client believes this has on their self-monitoring and emotion regulation. Such beliefs may, or may not, then be tested by changes in compliance, documented on the ANS tracker alongside the client's emotional and physiological state.

Getting out of SNS and DV

With most clients it is sufficient to stick to the conceptualisation of the three states as separate entities. However, if necessary and usually following feedback from the client, the concept of blends of states can be discussed. The simpler conceptualisation allows for an understanding that different strategies are needed to get out of SNS and DV. Most people will understand this experientially, if aware of their bodies, as SNS is associated with a need to move, whereas DV is recognised by a difficulty moving or a disconnection between oneself and the environment. The previously mentioned homework task of writing one's own definition of DV is helpful here, allowing client and therapist to review a range of experiences and determine the client's experience of DV. It is not unusual for the experience of DV to take a few sessions to clarify, as it can be a set of experiences that people are less familiar with attending to and articulating.

The strategies in this section are not intended to be a comprehensive list. Therapist and client are free to experiment, making the most of client's preferences and what is available. The spirit of curiosity and creativity is key; trying a strategy several times, alone and in combination, at different levels of SNS and DV, to ascertain its effectiveness. The use of external prompts is encouraged to circumvent habits and mindless/automatic behaviour. Post-it notes on kitchen cupboard doors and leaving resistance bands out in view would be two examples. If alarms throughout the day have been set to facilitate completion of the ANS tracker, clients could use the same prompt to practice strategies. Finally, for those clients who have watches that monitor their physiology, feedback about being stressed is a useful prompt to consider what they need to do to manage their autonomic state.

Strategies to Address SNS

- **Six Breaths per Minute**

When mobilised and yet not needing to flee or fight, the first thing to turn to is Six Breaths per Minute (6BPM). Most clients will go through a process of forgetting to use it when in SNS, then finding it effective at lower levels of anxiety, through to being able to use it when very anxious. The therapist should be open about this process, explaining it in terms of state and context dependent memory, celebrating successes along the way. Be vigilant of breath-holding, sighing and rapid breathing in sessions, as these allow for demonstration of monitoring and regulation while engaged in an activity. In cases where clients find it difficult to use this skill it is worth pairing with another, for example holding hands with a partner, looking at the natural world (the real thing or on a screen) or stroking a dog. Pairing can be discussed as a steppingstone to be used until the client becomes a little more skilled. A useful analogy is using stabilisers when learning to ride a bike.

- **Touch**

Moving on to think about soothing strategies that prompt the release of oxytocin, the therapist needs to have some awareness of the quality of the client's relationship in which they receive touch. We cannot assume romantic partners are supportive or caring. Equally, partners may be warm and yet the pattern of interaction can have been shaped by both parties over the years into one where touch is infrequent. Going through recent examples of how each partner responds to the other when in difficulty can be illuminating and present opportunities for trying something different. Interactions with children and pets can also be reviewed. While people may not be aware of the soothing influence, experimentation and documentation in the ANS tracker can yield useful data. Again, the experience of these is highly personal and if interaction with children provokes a spiral into self-criticism about being a bad parent, then this strategy is unlikely to be of benefit.

- **Engaging with Nature**

Given the large amount of data on the natural world activating VV, this is the third area to explore (Lee et al., 2014). It is not necessary to have the real thing, research on viewing pictures and videos on a screen has demonstrated a calming effect of the natural world. Thus, we can use this strategy, even when there isn't easy access to the outdoors. Get the client to think about environments they particularly like; for some of us it is the sound of the sea or the wind in the trees. If they are unsure, they can surf the net for video and audio footage of different environments and see what they respond to. Consideration needs to be given to all sense modalities; some clients will find pots of herbs particularly useful due to the smell, as well as being able to touch and look at them.

- **The Big Three Plus One**

Thomas R Lynch in his Radically Open Dialectical Behaviour Therapy Manual puts a number of well-known skills together here.

1. *EYEBROW WAG*

   Exercise: Imagine you are at a huge airport, and way off in the distance you see a friend who you feel very warmly towards and who you haven't seen for a long time. You start walking over towards each other. What would you say to them when you meet? Say it now as you would say it in this situation. And now say it again without moving your eyebrows.

   Discussion Point: What is the difference? How does each feel?

   Teaching Point: there is a complicated two-way relationship between the brain and the face, with the latter giving the brain information about how we feel. We can't feel surprised, pleased or affection if we don't have the eyebrow movement to provoke this. Wagging our eyebrows is a win-win, as we put those we are speaking to at ease. We are giving the viewer a 'no social threat' cue and we are also giving our own brain a 'no social threat' cue.

   Homework*:* experiment with wagging the eyebrows and see what impact it has on SNS.

2. *CLOSED MOUTH CO-OPERATIVE SMILE*

   Exercise: Let us both close our eyes, I'll talk you through the exercise and you can tell me what you noticed at the end. Put your mouth in a neutral position, notice how you feel emotionally, how you are breathing. Now, gently turn the corners of your mouth up into a warm broad smile; make sure it reaches your eyes but that you don't show your teeth. Notice if there have been any changes in how you feel emotionally, the way you're breathing or the colours you see behind your closed eyelids. Finally, let us turn the corners of our mouths down, sticking your bottom lip out very slightly and again checking in on the impact of this on our emotions and body. To end slowly do the warm broad smile again. Note – this exercise should take at least a minute, possibly two - don't rush it.

   Discussion Point: What did you notice? (Go through each of the three faces in detail, getting the client to comment on all of the changes they noticed).

   Teaching Point: Again, this demonstrates the two-way relationship between the face and our emotions as it impacts how we feel. This smile is broad, although we still do not see the teeth. It reaches the eyes, thereby making the corners crinkle. We are not aiming for an enigmatic smile, like the Mona Lisa, rather something that communicates warmth and can be maintained.

3. *DIAPHRAGMATIC BREATHING*

   This is pretty much the same principle as 6BPM covered earlier.

4. *PLUS-ONE – RELAXED BODY POSTURE*

Teaching Point: This is about using body posture to tell our ANS that we are safe. If seated it is about slouching or having your arms by your side, rather than protecting your torso by being side on or having your arms across it.

***Exercise*:** experiment with sitting in this position, client to feedback how it feels.

- **Chewing Gum**

Research has shown improvements in memory and decreases in stress resulting from chewing, as the body associates chewing with rest and digest, and therefore safety (Weijenberg et al., 2015). This is one of the ways in which eating is experienced as soothing. It may be worth clients trying chewing gum instead, however, there are several provisos with this strategy. Firstly, we do not want to encourage jaw-clenching as this turns on the trigeminal nerve, thereby turning off the VV. Secondly, we do want this to be a soothing rather than distracting strategy, and therefore how an individual reports its efficacy is of interest. This skill may be most appropriately utilised for those clients who are finding it hard to stop the habitual response of eating. It could be a steppingstone, paired with other skills, that gradually allows movement away from the consumption of food.

- **Exaggerated Movement and Facial Expression**

We can use a virtuous cycle when with other people of telling our own brain 'no social threat', communicating the same to the person we are interacting with and as a consequence, getting safety signals from them. When feeling threatened, we keep our arms and hands close into our bodies. Thus, we need to do the opposite; talking with our hand and ensuring that the elbows are away from the waist will provide safety signals to both ourselves and others around us. When alone, while we won't get the co-regulation from others, we can still flap our arms and legs, wag our eyebrows, and pull faces to give safety signals to the brain.

- **Ice Cold Water**

Putting one's eyes and forehead in ice water is known to activate the PNS (Hughes & Stoney, 2000; Khurana et al. 1980; Linehan et al.,2007). This skill tends to be one of last resort, and if clients haven't got a bowl of ice water to hand, the next best thing is to splash cold water on their face. Doing so, for some clients, can be the abrupt shock to the body that helps them get out of a very agitated or anxious state. It *should not* be used with clients where there is cardiac risk and should only be used for clients with a history of cardiac difficulties with medical approval. Clients frequently report it is an effective first strategy, which they then need to follow up with other soothing strategies. It appears to give them the ability to consider additional skills when they were not in a place to do so prior to the cold water.

Strategies to Address DV

- **Grounding**

Grounding can be achieved in a wide variety of ways. Firstly, we can ground ourselves in our bodies, systematically paying attention to different points of contact as we work our way up the body when we are in a sitting position. Grounding objects can be beneficial,

particularly small items that are kept in pockets and are consequently easily accessible, no matter where the client is. People often enjoy choosing the item, paying particular attention to look and feel, selecting properties they find aesthetically pleasing and/or have positive associations. Thirdly, it can be helpful for an individual to ground themselves in all sense modality using the 5-4-3-2-1 exercise. This involves listing 5 things one can see; 4 things that can be heard; 3 things that the person can touch; 2 things they can smell in the moment and 1 thing that can be tasted. Such a strategy is helpful when reorientating to the current environment

- **Self-Hug**

It is worth asking clients whether they already engage in this activity prior to covering it with them. When you do so, make sure you practice it together. Most people will naturally put one hand on their shoulder and the other on their ribs just below the shoulder. Make sure that clients tune in to how it feels when practicing together. Can they describe their response and what happens to their breathing? We can also add rocking to this or use separately. Most of us intuitively know that rocking is soothing, as we do it with small children and babies when they are distressed. Again, practice together and see how the client experiences it. They may have preference for trying it when in SNS or DV – start with their suggestion.

- **Exercise**

Given that DV is the immobilisation system and that the power supply has been severely restricted so that only very basic functions are running, the therapist's job is to support the client to reconnect with themselves and the outside world. Moving is part of this but caution needs to be exercised as clients need to be safe to move. Thus, think about a graded approach here, dependent on what the individual believes they can do and the results of the experiments for homework. Being frozen in front of the computer when at home and working in a very quiet environment was frequently reported during the COVID-19 lockdowns. Movement, starting with looking at and stroking a houseplant, followed by standing, stretching (whilst having a stable support) and then walking, is one example. The client may go further by climbing a staircase, having a brisk walk around the block or garden, but *only* after stepping it up and ensuring they are safe to do so.

- **Exercise with Added Feedback**

Giving the body additional feedback also appears to be beneficial when in DV. Press-ups (adapted to the client's ability), either on the floor or against a wall, allows for a larger number of points of contact, additional muscle activation and, in some instances, a change in posture. Clients can also use resistance bands to achieve similar effects. We aren't talking about a full workout here, rather a few minutes making the most of what the current or neighbouring environments give access to.

- **Exercise in Nature**

Many clients report that exercise that can be done in nature is a particularly useful combination. Again, think about utilising all sense modalities here. Consider whether listening to a podcast is helpful or if it would be more effective to listen to the sounds of nature, being as present as one can in the garden or park. If green spaces are not available, can clients walk down quieter roads where birds can be heard, looking out for the occasional tree or what is in a garden? If this is not possible, can clients walk while listening to sounds of nature?

NOTE: It is possible that *some* of the skills in SNS may be of use when in DV. It is important not to use 6 BPM or other skills that slow things down. However, some clients may find the eyebrow wag, cooperative smile etc. useful. It is a matter of trial and error, getting the client to note down the effects and carefully reviewing the details together.

Consolidation and Relapse Prevention

In preparation for the last session the client can be asked to review their notes and ANS tracking documents to answer the following four questions.

A) What have I learnt?
B) What do I need to keep on doing differently?
C) What will trip me up?
D) How will I manage this?

Clients may also wish to specify how they intend to progress their work further. A more detailed plan is preferable, the therapist adding their suggestions to the client's answers to the above.

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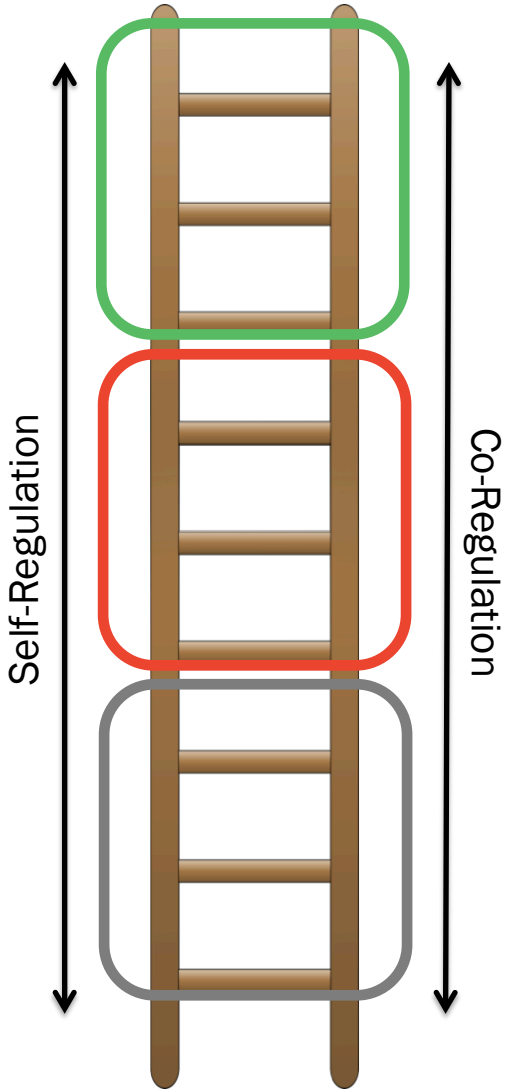
Appendix M

PVTT Therapy Manual Appendix 1



VENTRAL VAGAL – *safe & social*

I can see the 'big picture' feel connected to the world and the people in it. I can take in the faces of friends, tune into conversations and out of distracting noises. I might describe myself as happy, active, curious, interested and the world as safe, fun and peaceful. I am connected to my experiences and can reach out to others. I feel organised, I can follow through with plans, take care of myself and take time to play, do things with others and feel productive in my work. Our heart rate is regulated and our breath is full.

SYMPATHETIC NERVOUS SYSTEM – *mobilised, fight or flight*

'Fear is whispering to me and I feel the power of its message. Move, take action, escape. No one can be trusted. No place is safe'

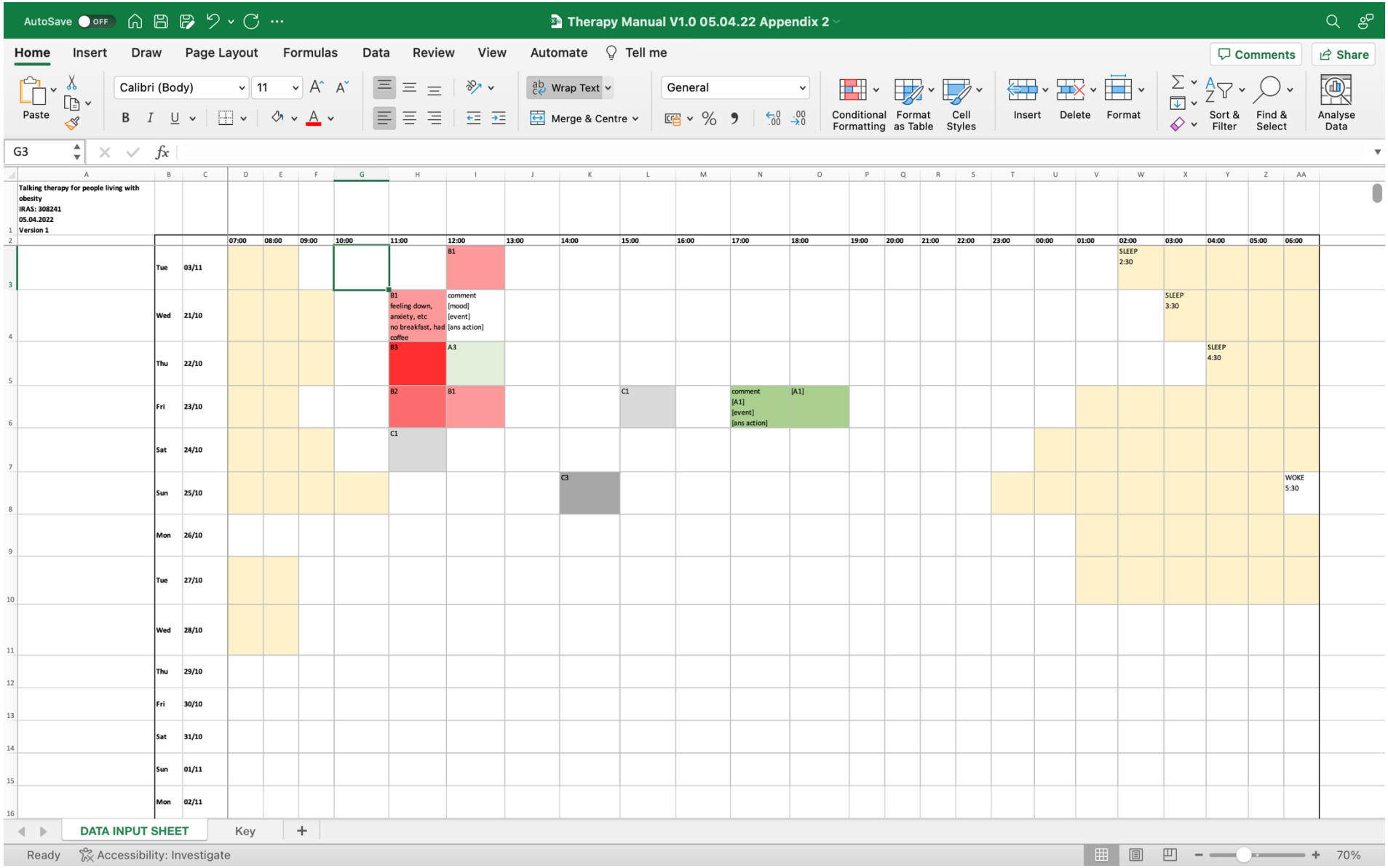
A stirring sense of unease. We go into action, Our heart rate speeds up, our breath is short and shallow, we scan the environment for danger. I might describe myself as anxious or angry and feel a rush of adrenaline which makes it hard for me to be still. The world may feel dangerous, chaotic or unfriendly. I feel I need to protect myself from harm. This can mean I experience anxiety, panic attacks, anger, inability to focus or follow through and distress in relationships.

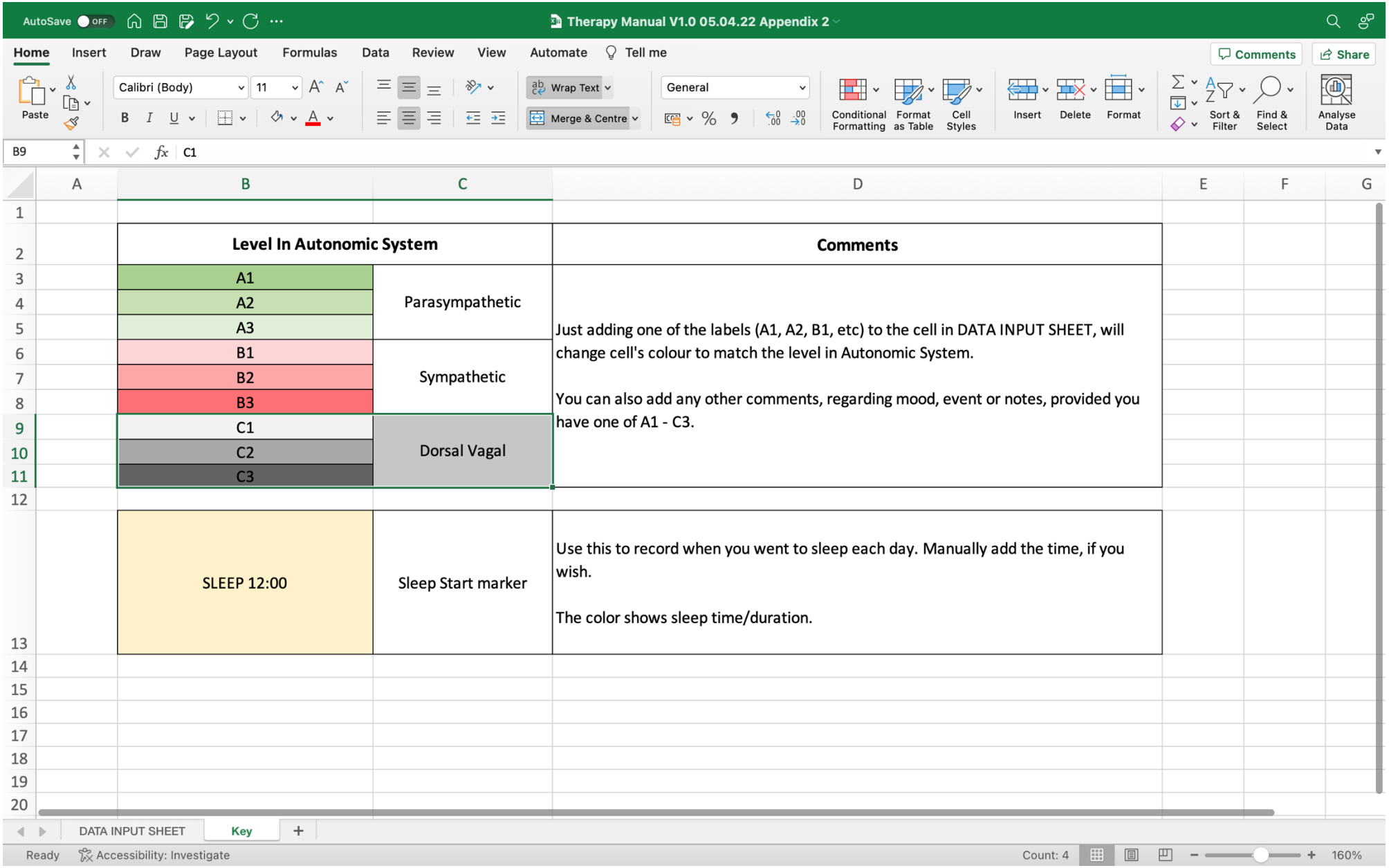
DORSAL VAGAL – *immobilised, collapsed*

It is the path of last resort, when all else fails and I feel trapped and hopeless. I am alone with my despair and escape into not knowing, not feeling and almost a sense of not being. I might describe myself as hopeless, abandoned, numb, foggy, too tired to think or act and the world is empty, dead and dark. My mind and body have moved into conservation mode. I may experience dissociation, problems with memory, depression, isolation and no energy for the tasks of daily living.

Appendix N

PVTT Therapy Manual Appendix 2

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Therapy Manual V1.0 05.04.22 Appendix 2
Home Insert Draw Page Layout Formulas Data Review View Automate Tell me
Comments Share
Paste
Calibri (Body) 11
Wrap Text
General
Merge & Centre
Conditional Formatting
Format as Table
Cell Styles
Insert Delete Format
Sort & Filter
Find & Select
Analyse Data
B9
C1
Level In Autonomic System
Comments
A1
A2
A3
Parasympathetic
B1
B2
B3
Sympathetic
C1
C2
C3
Dorsal Vagal
Just adding one of the labels (A1, A2, B1, etc) to the cell in DATA INPUT SHEET, will change cell's colour to match the level in Autonomic System.
You can also add any other comments, regarding mood, event or notes, provided you have one of A1 - C3.
SLEEP 12:00
Sleep Start marker
Use this to record when you went to sleep each day. Manually add the time, if you wish.
The color shows sleep time/duration.
DATA INPUT SHEET
Key
Ready
Accessibility: Investigate
Count: 4
160%

Appendix O

Treatment Fidelity Measure

PVT for Bigger Bodies – Treatment Fidelity Scale

This rating scale uses 6 items from the Cognitive Therapy Rating Scale-Revised (Blackburn, James, & Reichelt, 2001). Agenda setting, feedback, collaboration, pace, interpersonal effectiveness, and homework setting. Three items have been added particular to the PVT manual: psychoeducation, skills teaching and review of tracking. As with the CTS-R, the Dreyfus scale is used for denoting competence. Given that depending on the session, it may be appropriate to omit psychoeducation or reviewing tracking and these can be marked as not applicable. Thus, competence is denoted by 50% of a variable possible total score.

0: Absence of feature, or highly inappropriate performance

1: Inappropriate performance, with major problems evident

2: Evidence of competence, but numerous problems and lack of consistency

3: Competent, but some problems and/or inconsistencies

4: Good features, but minor problems and/or inconsistencies

5: Very good features, minimal problems and/or inconsistencies

6: Excellent performance, even in the face of client difficulties

The present scale has incorporated the Dreyfus system (Dreyfus, 1989) for denoting competence, which is described fully in the manual. Please note that the 'top marks (i.e., near the 'expert' end of the continuum) are reserved for those therapists demonstrating highly effective skills, particularly in the face of difficulties (i.e., highly aggressive or avoidant clients; high levels of emotional discharge from the clients; and various situational factors).

The “Key Features” describe the important features that need to be considered when scoring each item. When rating the item, you must first identify whether some of the features are present. You must then consider whether the therapist should be regarded as competent with the features. If the therapist includes most of the key features and uses them appropriately (i.e., misses few relevant opportunities to use them), the therapist should be rated very highly.

It is important to remember that the scoring profile for this scale should approximate to a normal distribution (i.e., mid-point 3), with relatively few therapists scoring at the extremes.

ITEM 1 - AGENDA SETTING & ADHERENCE

Key features: To address adequately topics that have been agreed and set in an appropriate way. This involves the setting of discrete and realistic targets collaboratively. The format for setting the agenda may vary according to the stage of therapy - see manual.

Three features need to be considered when scoring this item:

(i) presence/absence of an agenda which is explicit, agreed, and prioritised, and feasible in the time available.

(ii) appropriateness of the contents of the agenda (to stage of therapy, current concerns etc.), a standing item being a review of the homework set previously.

(iii) appropriate adherence to the agenda.

ITEM 2 - FEEDBACK

Key features: The client's and therapist's understanding of key issues should be helped through the use of two-way feedback: The two major forms of feeding back information are through general summary and chunking of important units of information. The use of appropriate feedback helps both the therapist to understand the client's situation, and the client to synthesise material enabling him/her to gain major insight and make therapeutic shifts. It also helps to keep the client focused.

Three features need to be considered when scoring this item:

(i) presence and frequency, or absence, of feedback. Feedback should be given/elicited throughout the therapy - with major summaries both at the beginning (review of week) and end (session summary), while topic reviews (i.e., chunking) should occur throughout the session.

(ii) appropriateness of the contents of the feedback.

(iii) manner of its delivery and elicitation (NB: can be written).

ITEM 3 - COLLABORATION

Key features: The client should be encouraged to be active in the session. There must be clear evidence of productive teamwork, with the therapist skilfully encouraging the client to participate fully (e.g., through questioning techniques, shared problem solving and decision making) and take responsibility. However, the therapist must not allow the client to ramble in an unstructured way.

Three features need to be considered: the therapist style should encourage effective teamwork through his/her use of:

(i) verbal skills (e.g., non-hectoring).

(ii) non-verbal skills (e.g., attention and use of joint activities).

(iii) sharing of written summaries.

ITEM 4 - PACING AND EFFICIENT USE OF TIME

Key features: The session should be well 'time managed' in relation to the agenda, with the session flowing smoothly through discrete start, middle, and concluding phases. The work must be paced well in relation to the client's needs, and while important issues need to be followed, unproductive digressions should be dealt with smoothly. The session should not go over time, without good reason.

Three features need to be considered:

(i) the degree to which the session flows smoothly through the discrete phases.

(ii) the appropriateness of the pacing throughout the session.
(iii) the degree of fit to the learning speed of the client.

ITEM 5 - INTERPERSONAL EFFECTIVENESS

Key features: The client is put at ease by the therapist's verbal and non-verbal (e.g., listening skills) behaviour. The client should feel that the core conditions (i.e., warmth, genuineness, empathy and understanding) are present. However, it is important to keep professional boundaries. In situations where the therapist is extremely interpersonally effective, he/she is creative, insightful, and inspirational.

Three features need to be considered:
(i) empathy - the therapist is able to understand and enter the client's feelings imaginatively and uses this understanding to promote change.
(ii) genuineness - the therapist has established a trusting working relationship.
(iii) warmth - the client seems to feel liked and accepted by the therapist.

ITEM 6 – PSYCHOEDUCATION

Three features need to be considered:
(i) The ANS Hierarchy.
(ii) Respect shown for shifts in the hierarchy.
(iii) Client's observations – the client reports their experience of VV, SNS, DV, including all elements of physiology.

ITEM 7 – REVIEW OF TRACKING

Three features need to be considered:
(i) ANS tracker reviewed.
(ii) Attention particularly paid to in-the-moment shifts in ANS, up and down the ladder, considering triggers AND/OR coping strategies.
(iii) Efficacy of coping strategy/strategies are discussed.

ITEM 8 – SKILLS TEACHING

Three features need to be considered:
(i) Demonstration of skills.
(ii) Rehearsal of skills.
(ii) Planning practice of skills.

ITEM 9 - HOMEWORK SETTING

Key features: This aspect concerns the setting of an appropriate homework task, one with clear and precise goals. The aims should be to negotiate an appropriate task for the stage of therapy in line with the conceptualisation; to ensure the client understands the rationale for undertaking

the task; to test out ideas, try new experiences, predict, and deal with potential obstacles, and experiment with new ways of responding.

There are three aspects to this item:

(i) presence/absence of a homework task in which clear and precise goals have been set.
(ii) the task should be derived from material discussed in the session, such that there is a clear understanding of what will be learnt from performing the task.
(iii) the homework task should be set jointly, and sufficient time should be allowed for it to be explained clearly (i.e., explain, discuss relevance, predict obstacles, etc.).

Appendix P

Trended Range Graphs

Figure P1.1

Participant A Trended Range Graph for VAS Body Awareness

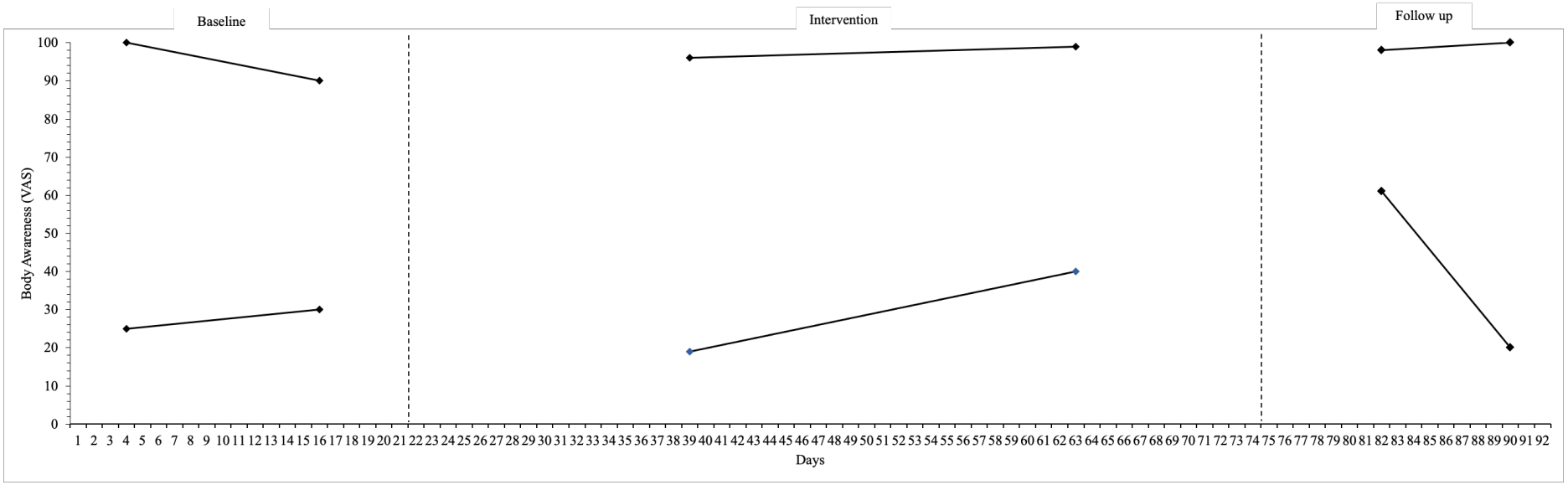


Figure P1.2

Participant A Trended Range Graph for VAS Emotion Regulation

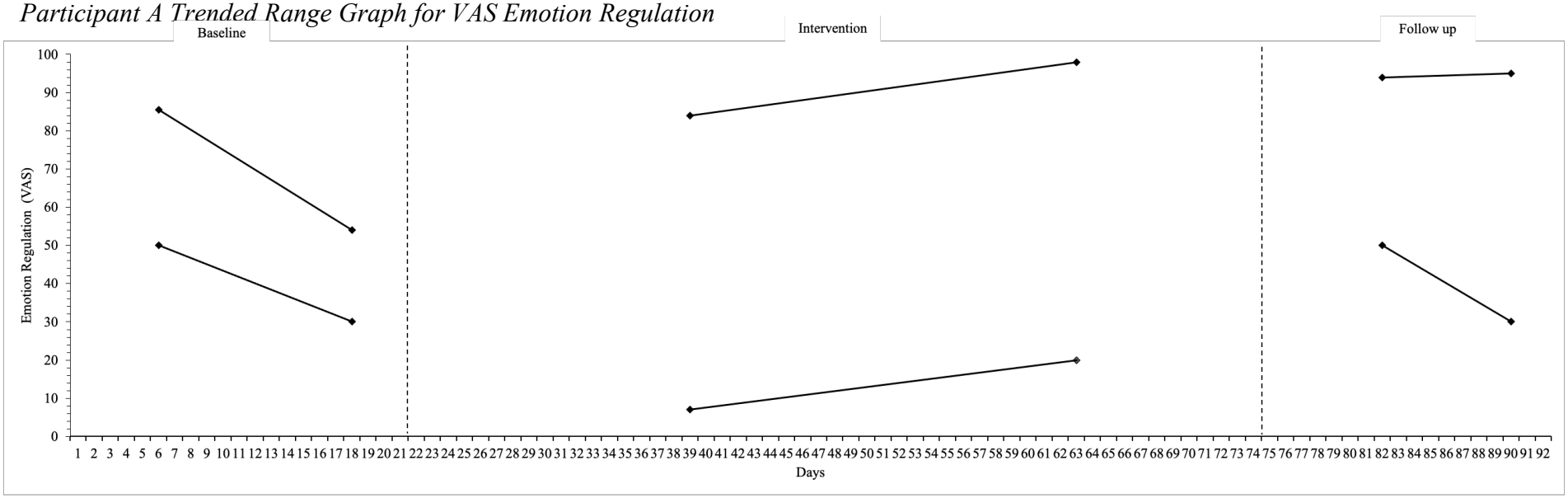


Figure P1.3

Participant A Trended Range Graph for VAS Chosen Behaviour

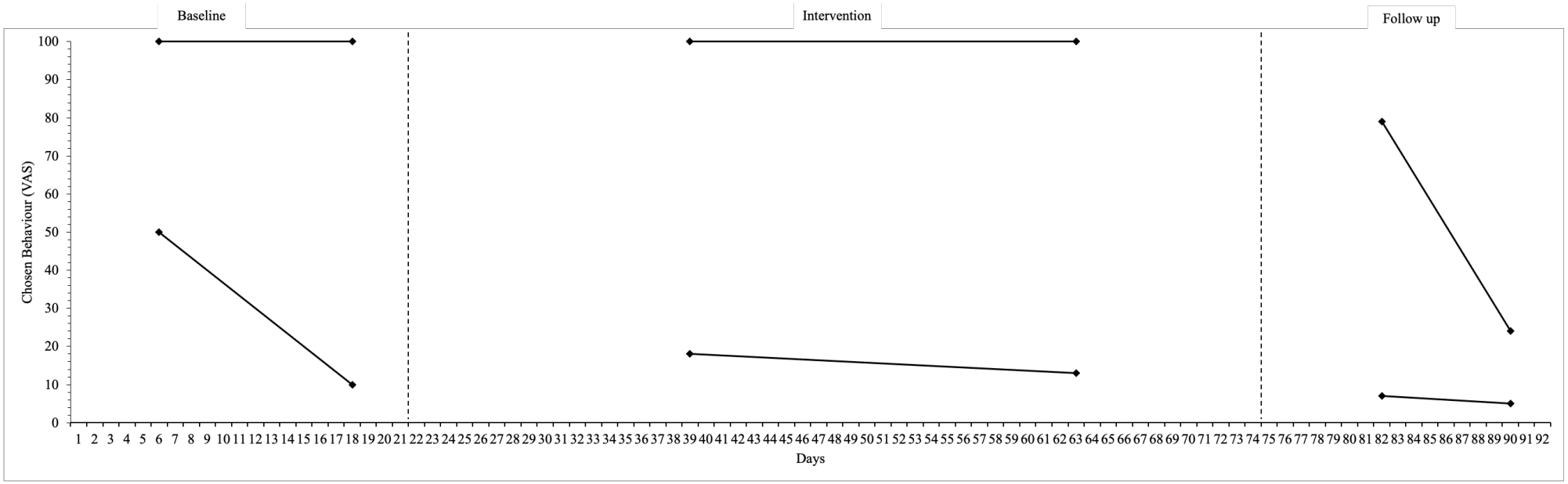


Figure P1.4

Participant A Trended Range Graph for HRV - RMSSD

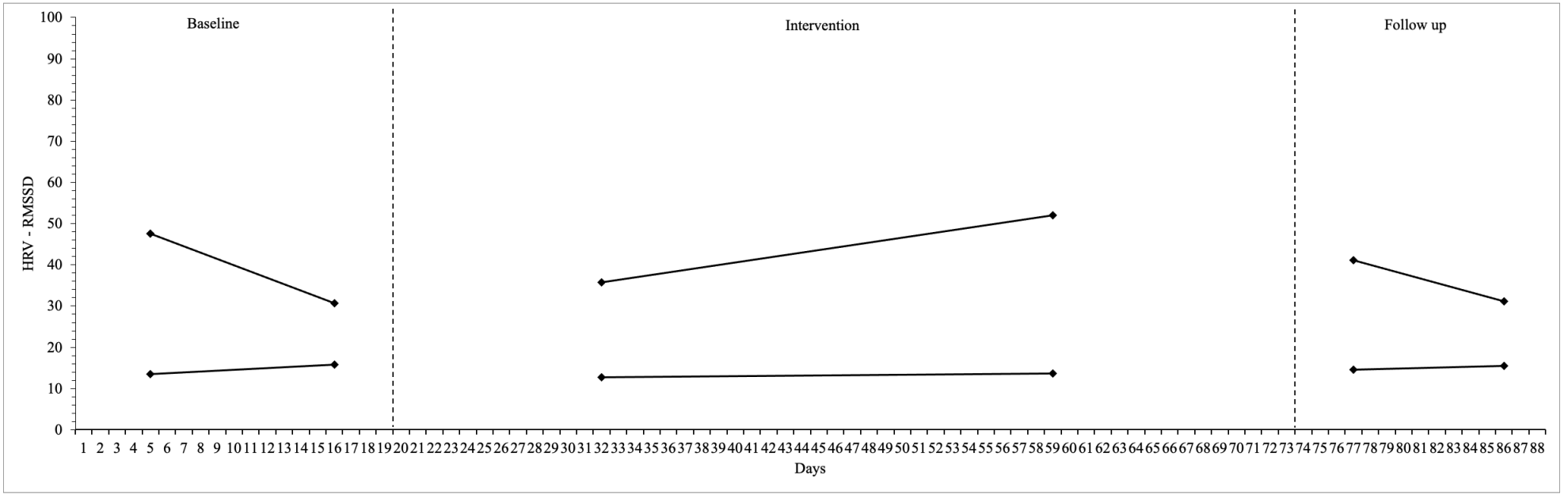


Figure P2.1

Participant B Trended Range Graph for VAS Body Awareness

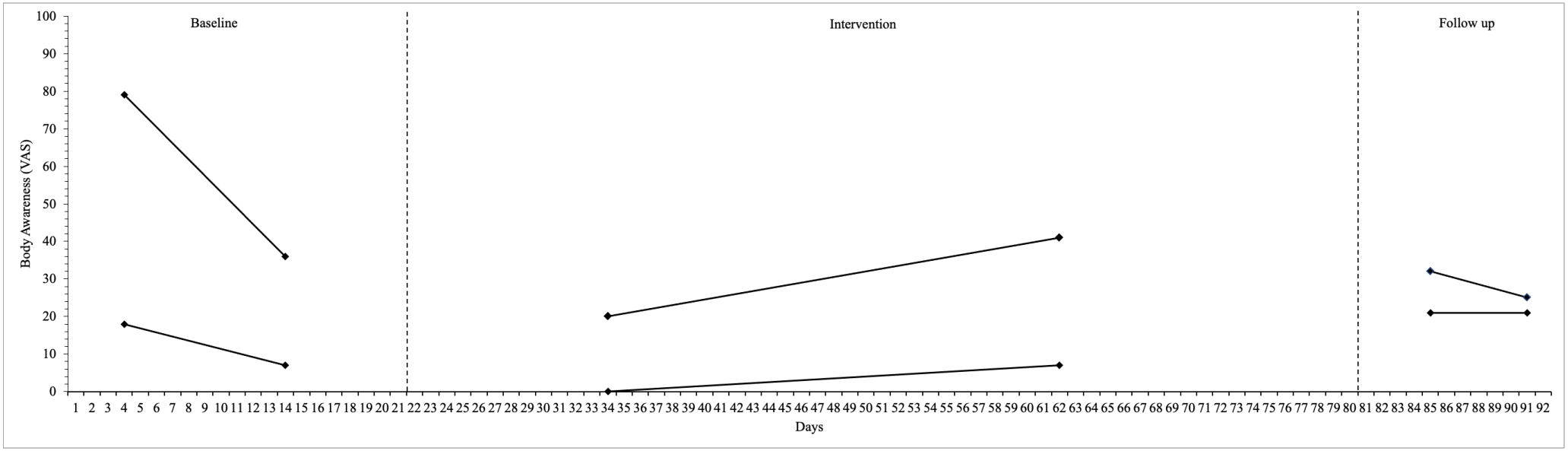
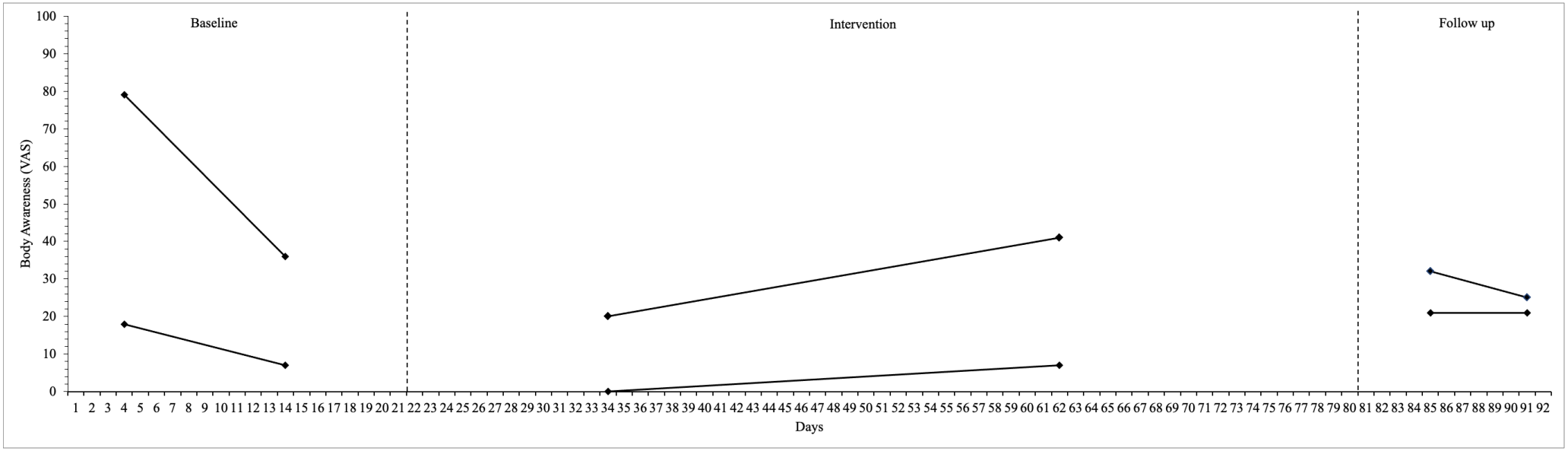


Figure P2.2

Participant B Trended Range Graph for VAS Emotion Regulation



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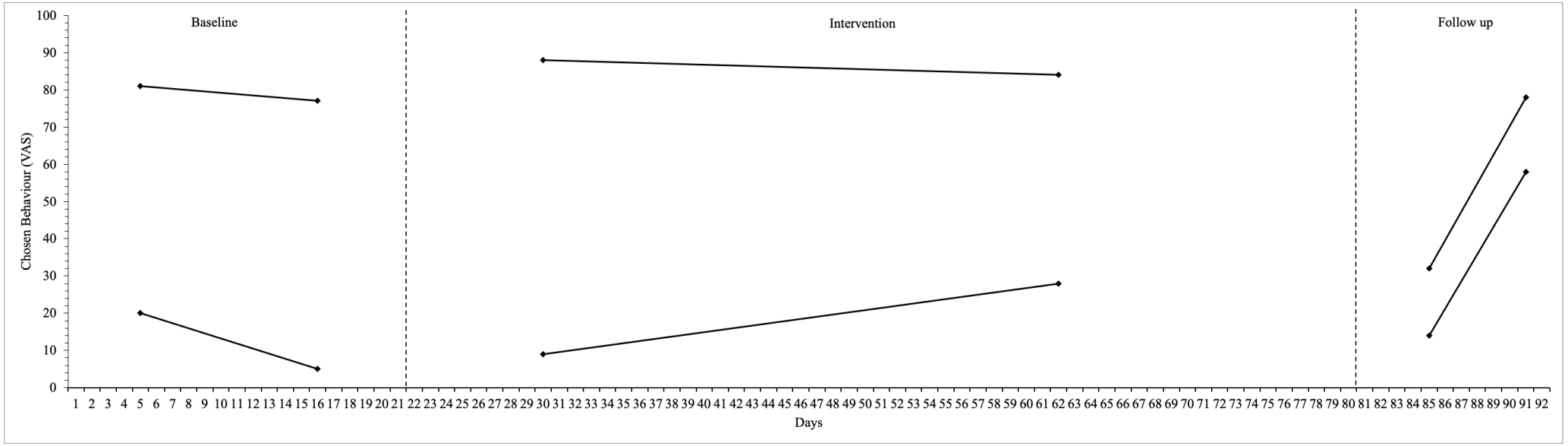
Participant B Trended Range Graph for VAS Chosen Behaviour



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Participant B Trended Range Graph for HRV - RMSSD

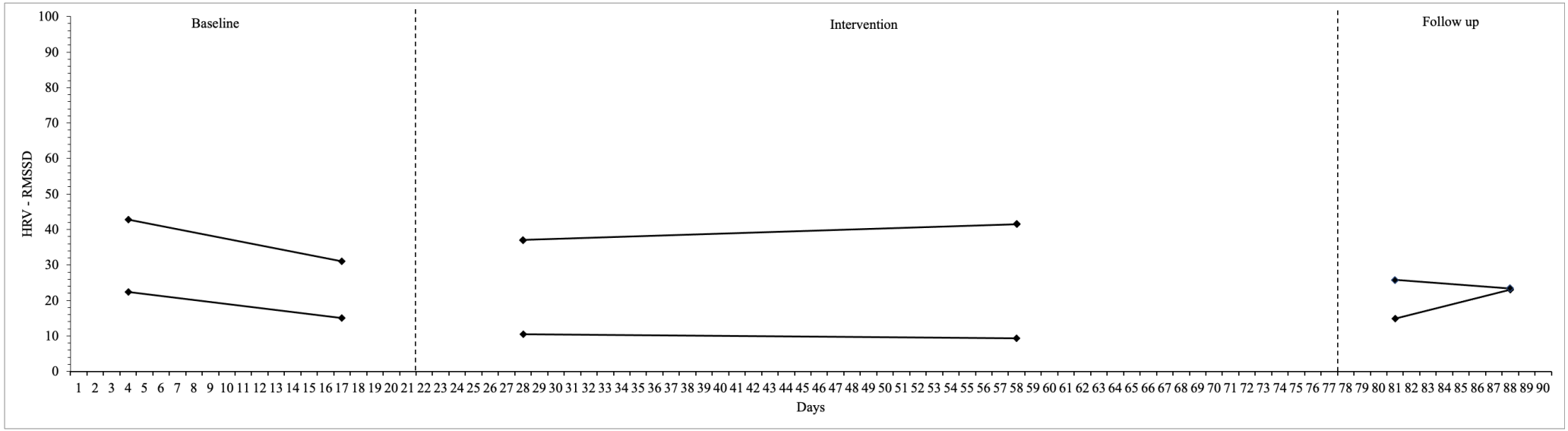


Figure P3.1

Participant C Trended Range Graph for VAS Body Awareness

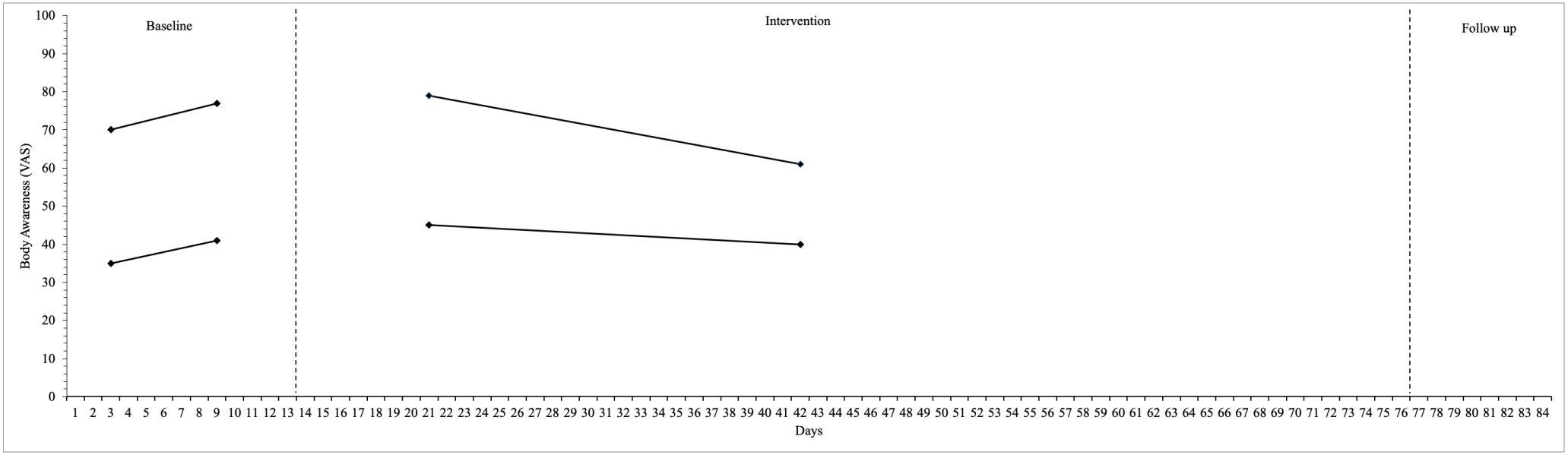
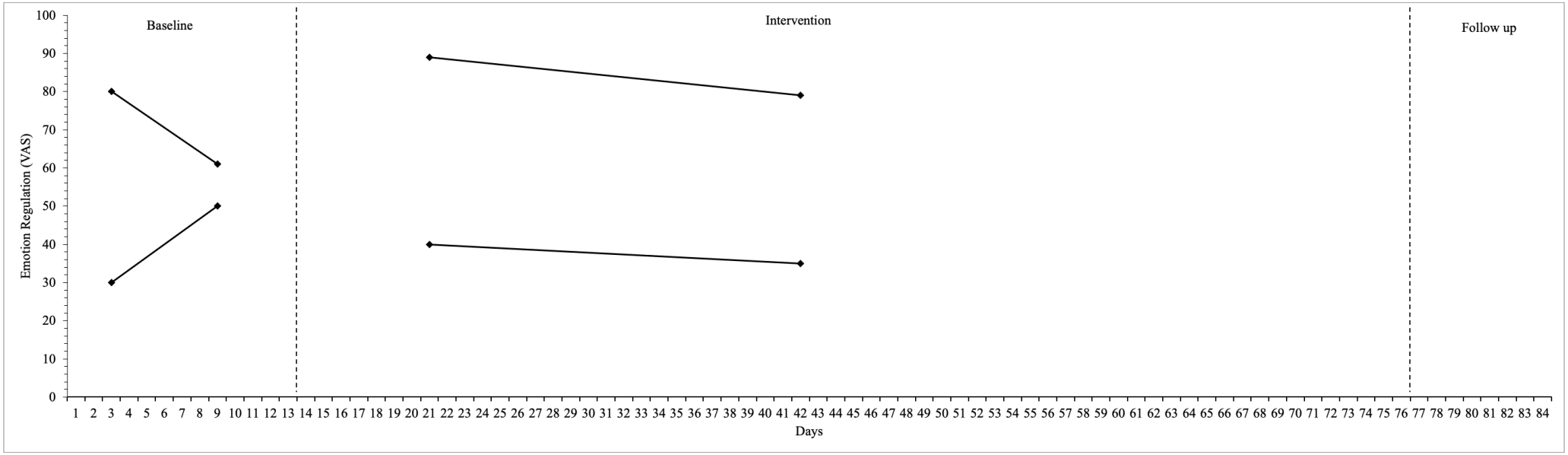


Figure P3.2

Participant C Trended Range Graph for VAS Emotion Regulation



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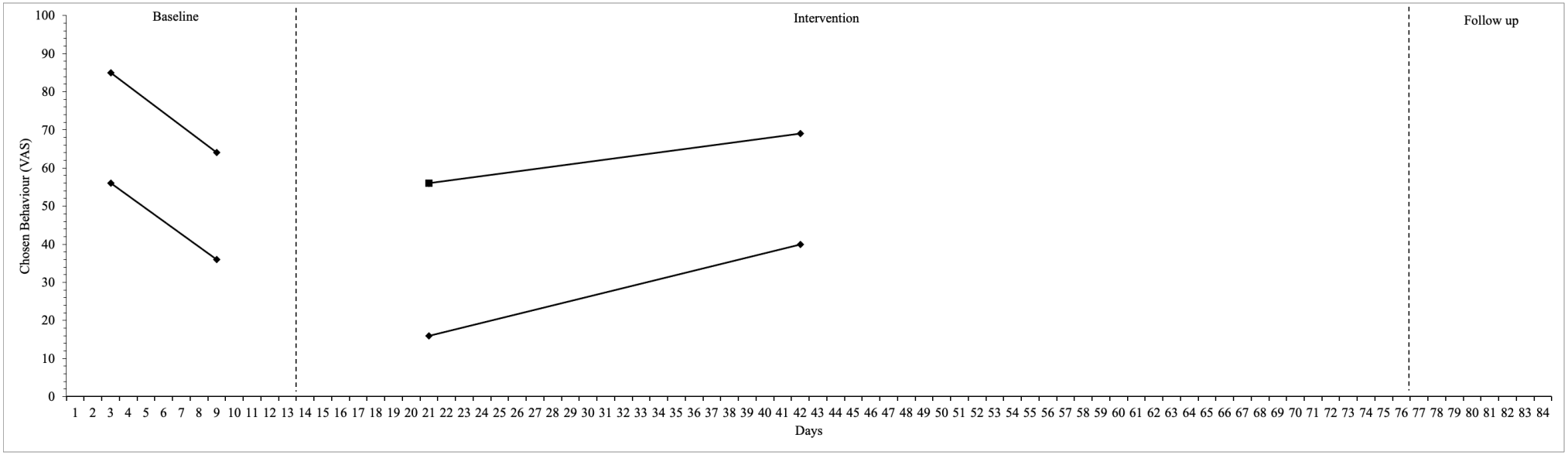


Figure P3.4

Participant C Trended Range Graph for HRV - RMSSD

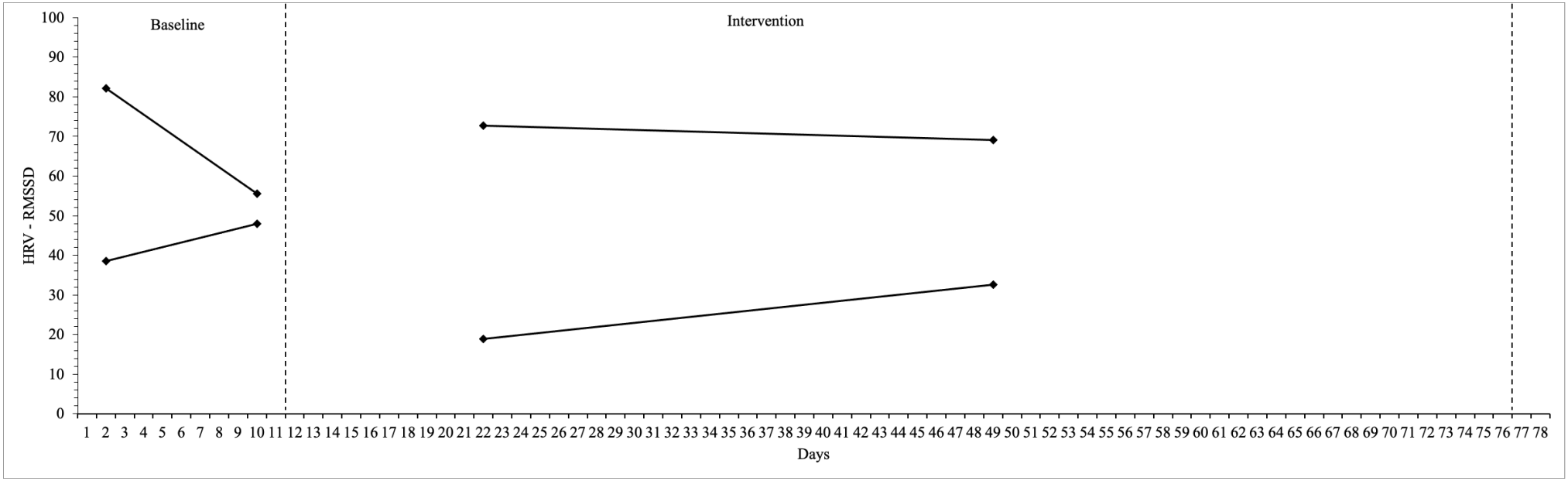
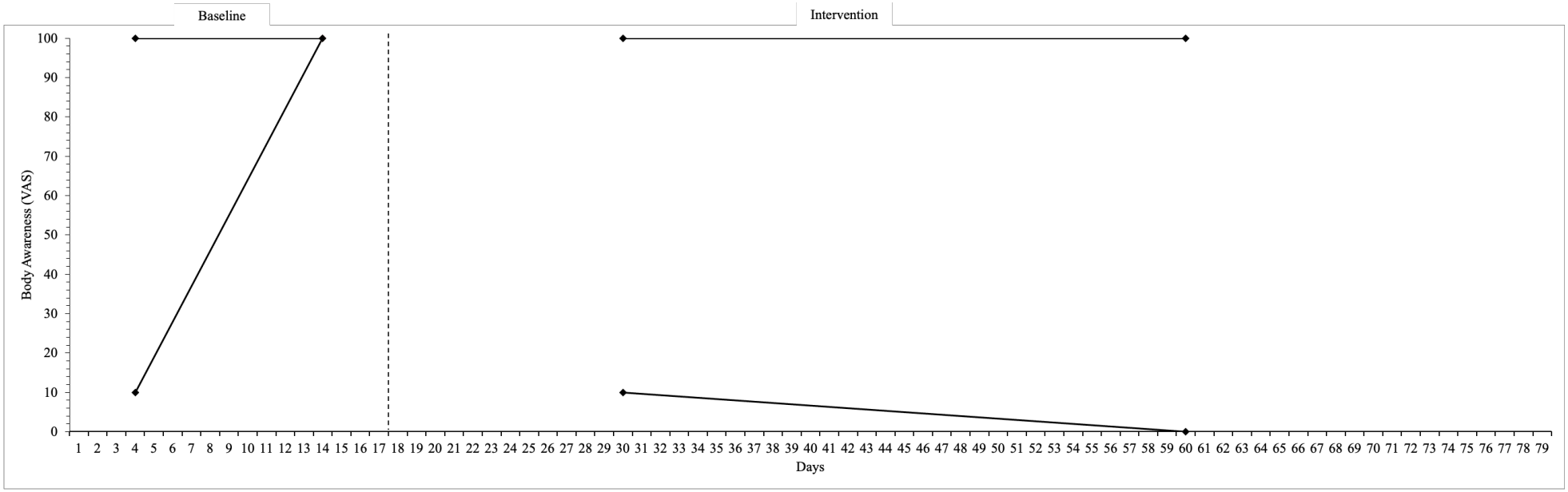


Figure P4.1

Participant D Trended Range Graph for VAS Body Awareness



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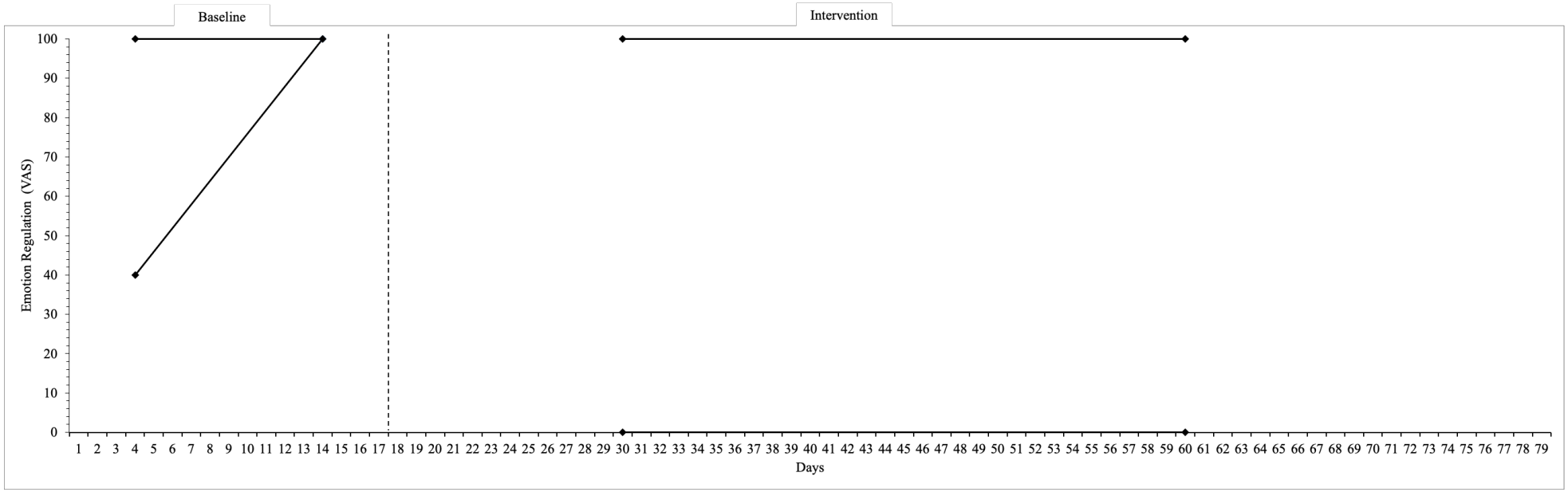
Participant D Trended Range Graph for VAS Emotion Regulation



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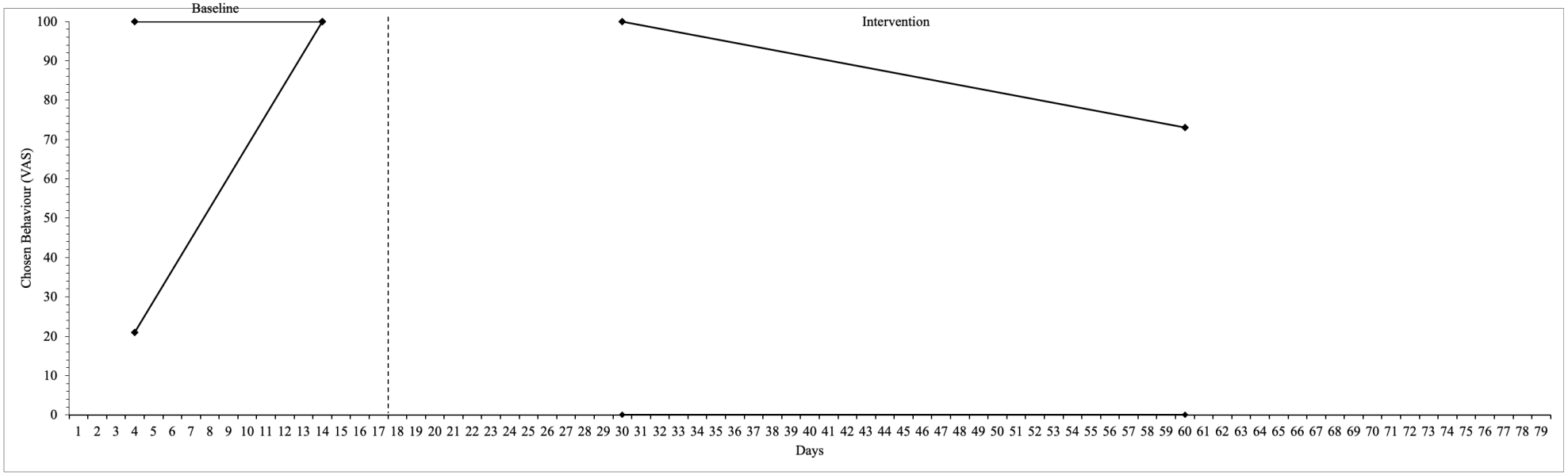

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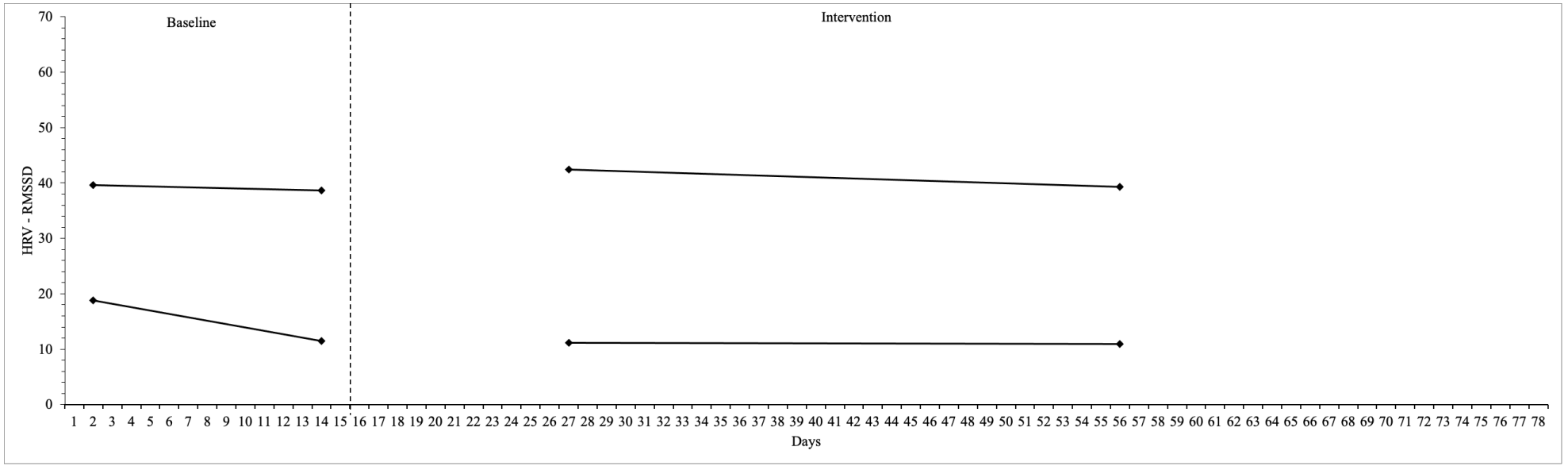

Figure P5.1

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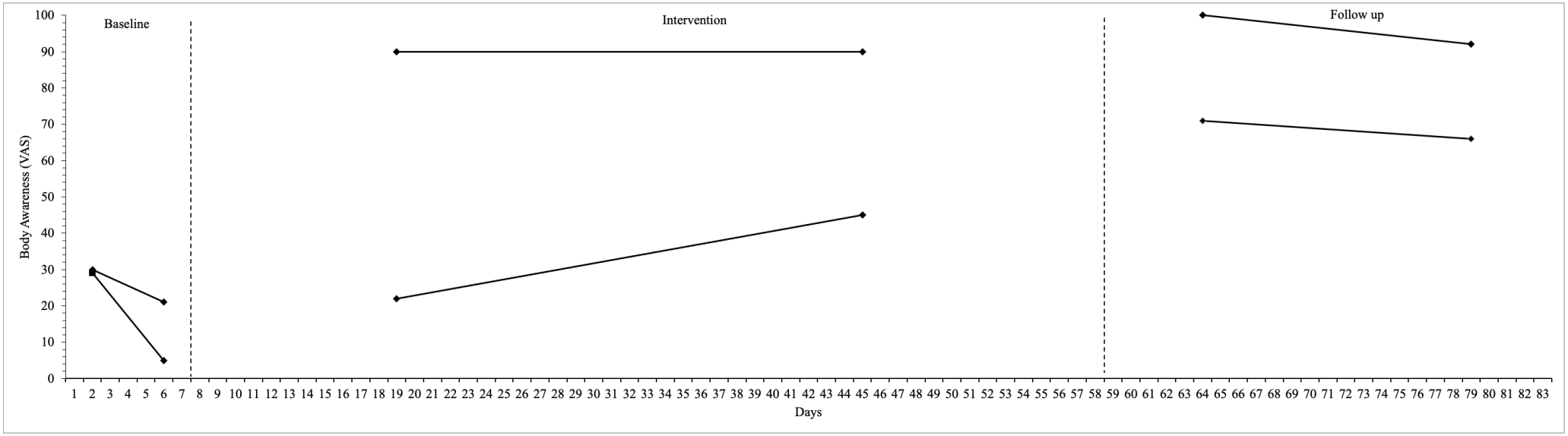
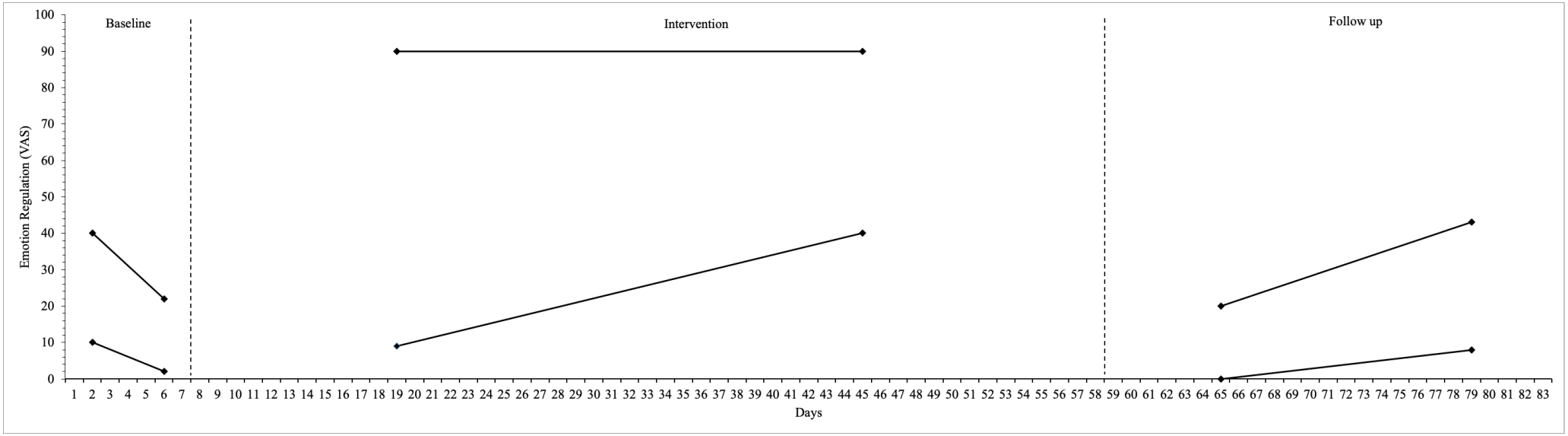


Figure P5.2

Participant E Trended Range Graph for VAS Emotion Regulation



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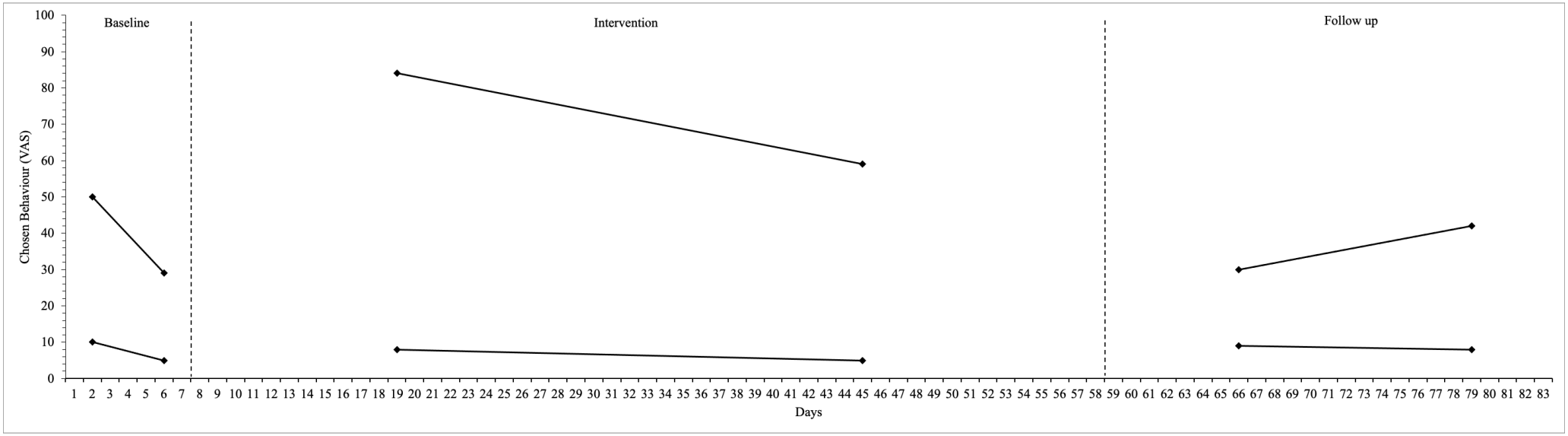
Participant E Trended Range Graph for VAS Chosen Behaviour



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Participant E Trended Range Graph for HRV - RMSSD

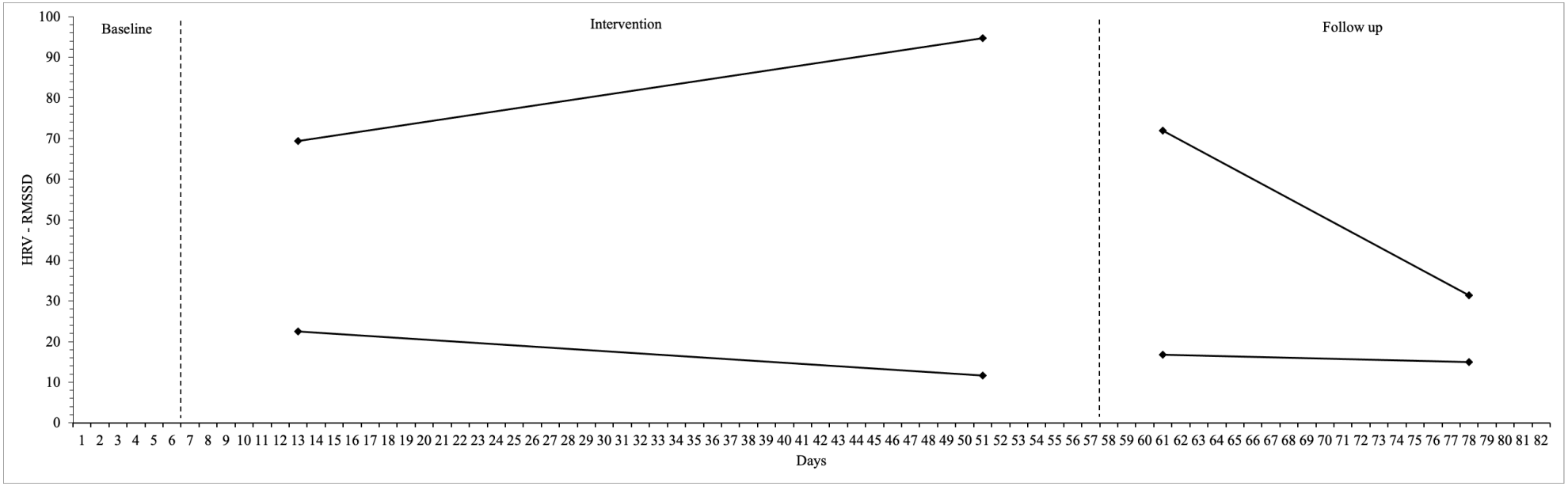
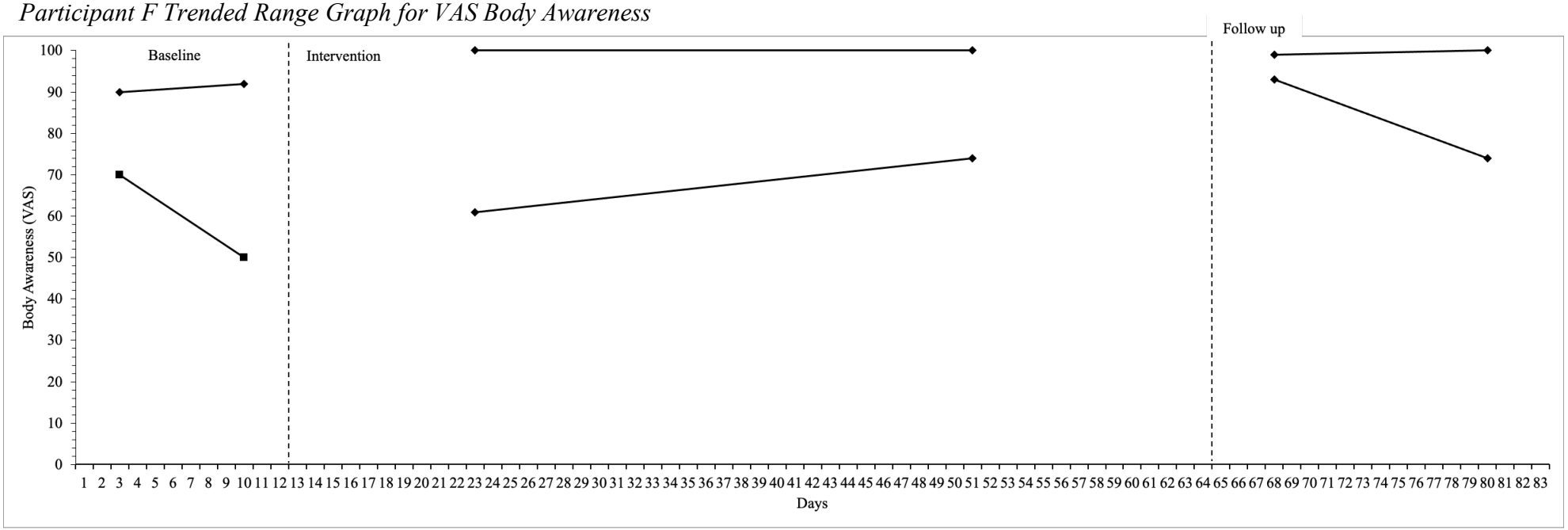


Figure P6.1

Participant F Trended Range Graph for VAS Body Awareness



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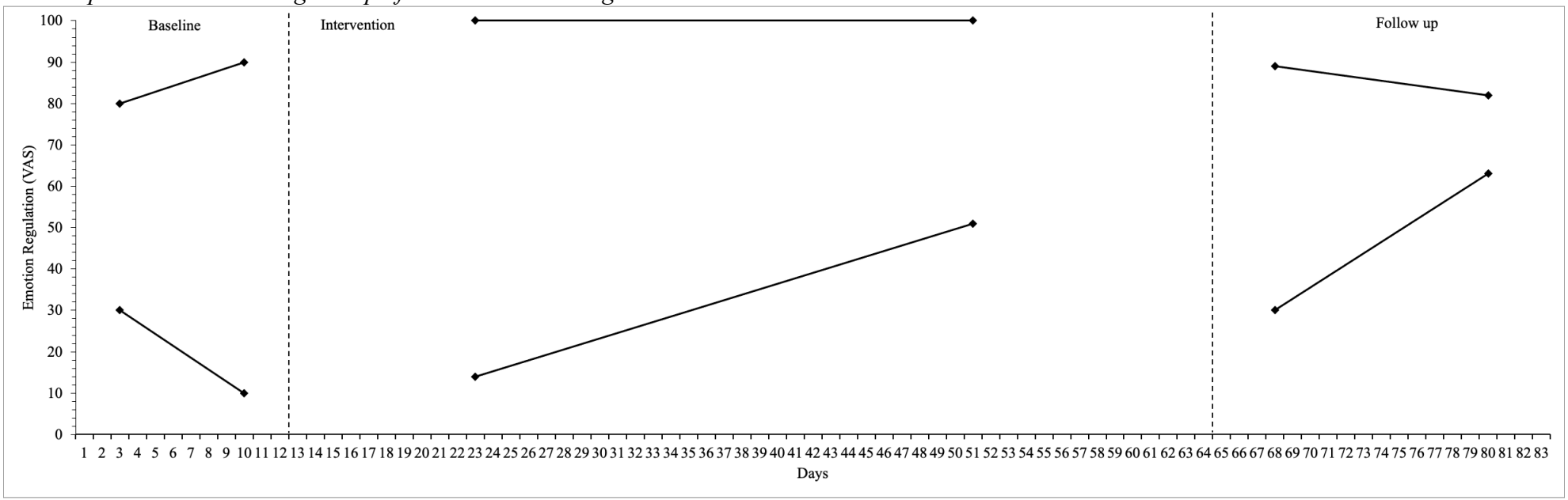

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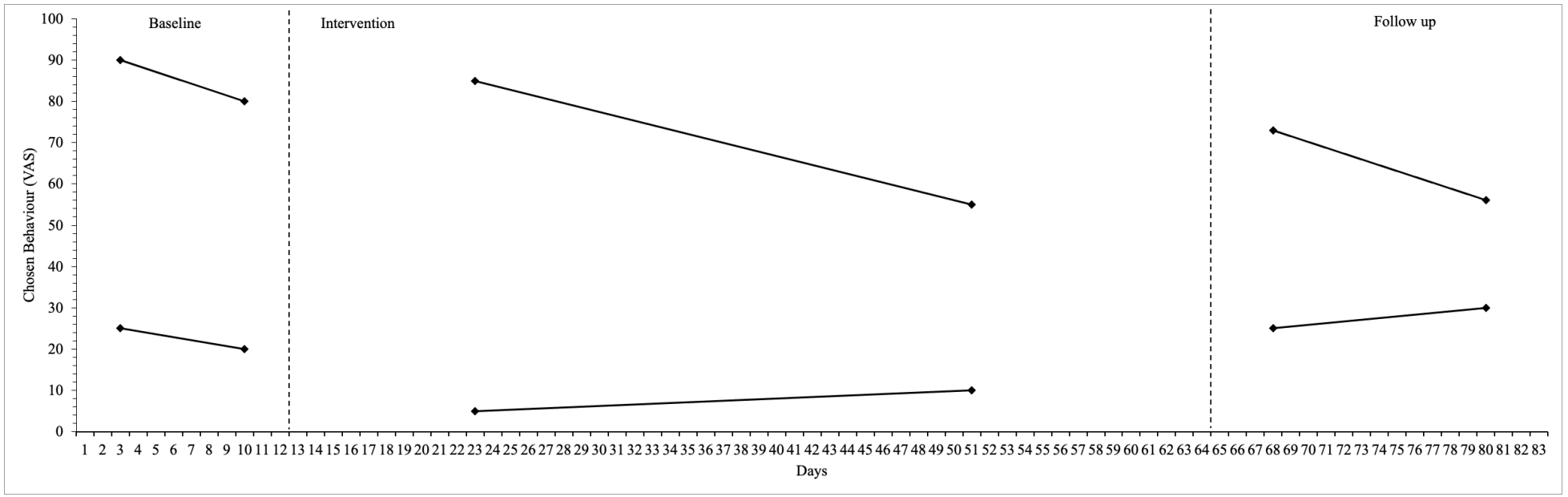


Figure P6.4

Participant F Trended Range Graph for HRV - RMSSD

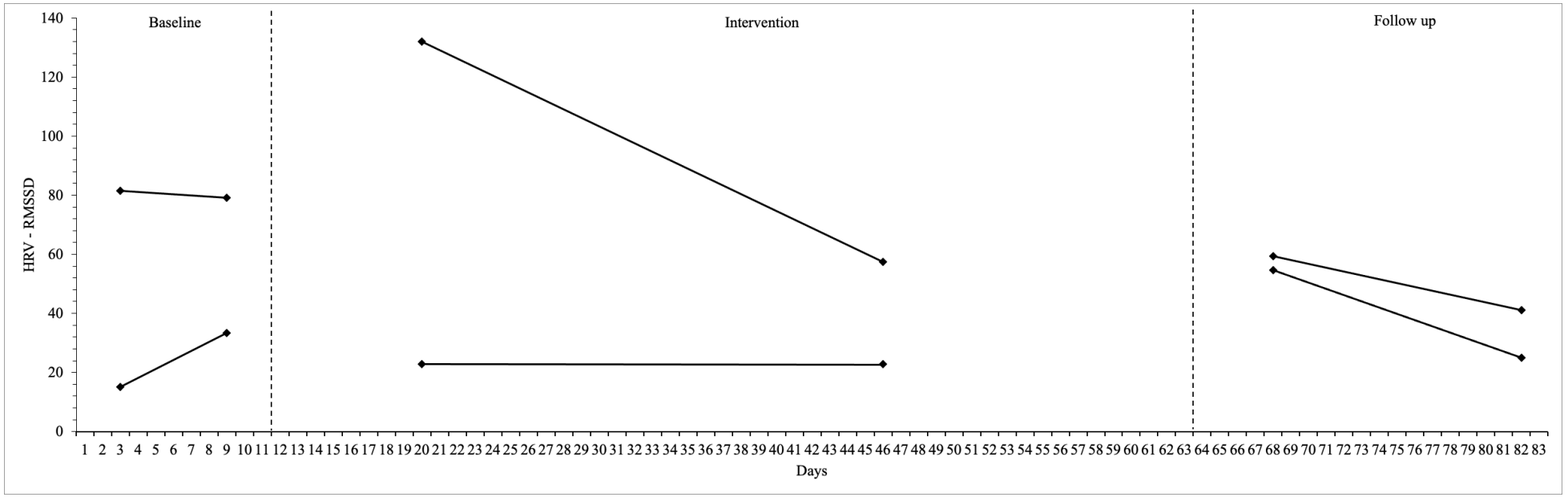
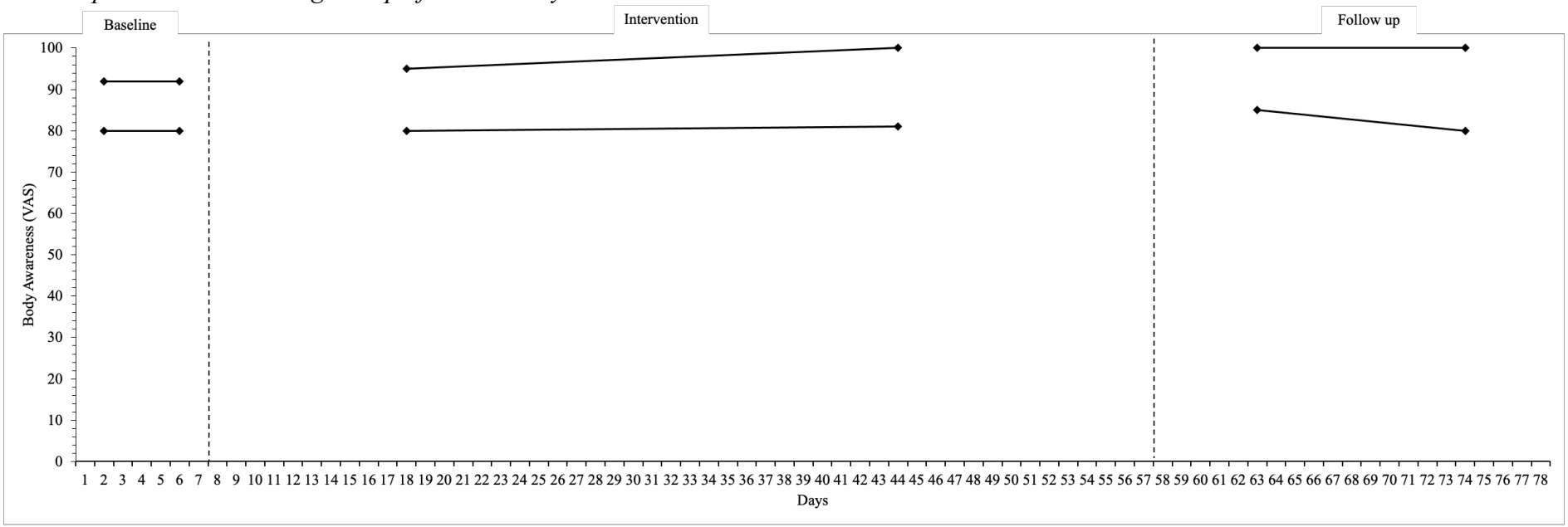


Figure P7.1

Participant G Trended Range Graph for VAS Body Awareness



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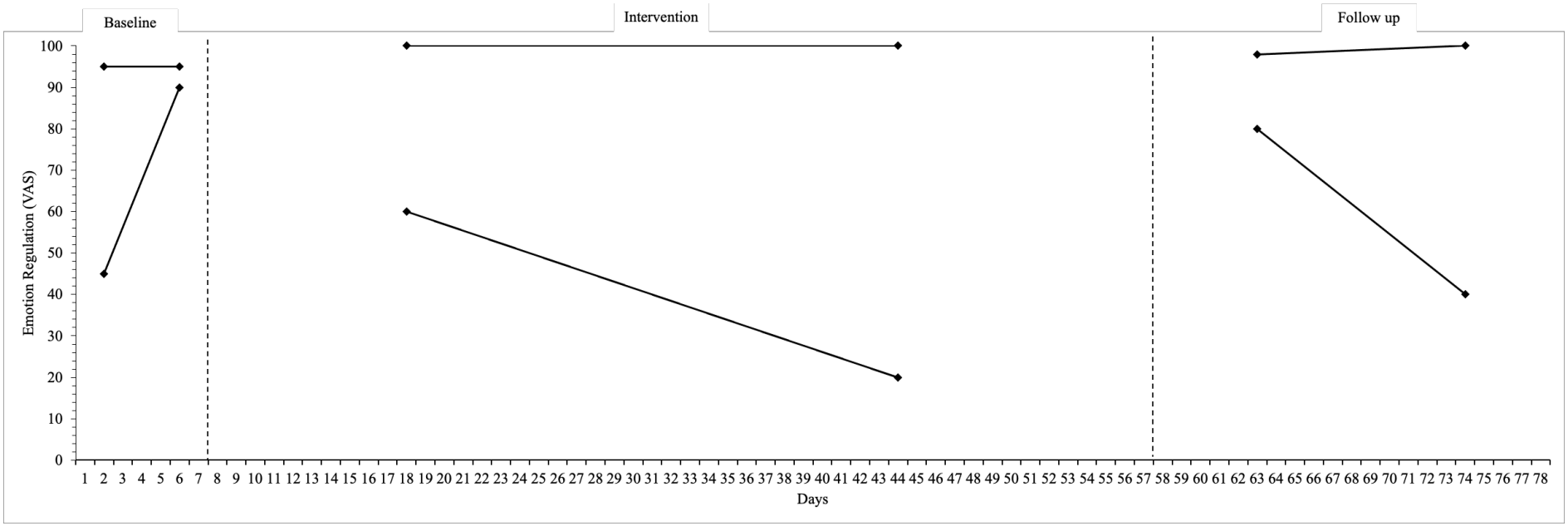

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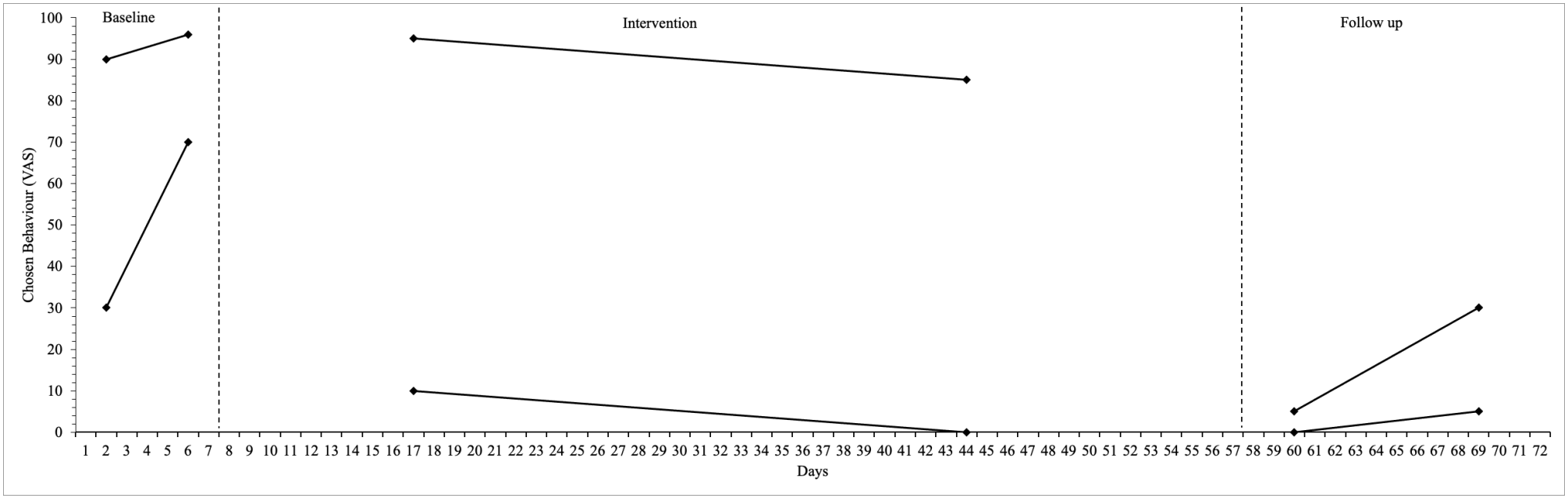

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Participant G Trended Range Graph for HRV - RMSSD

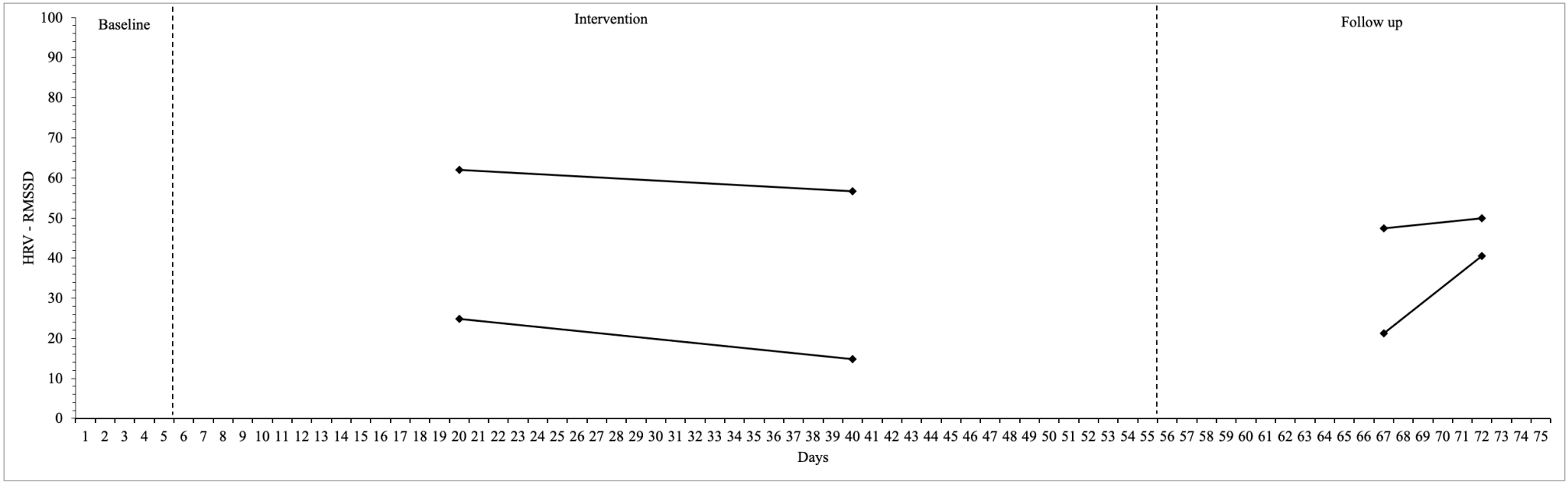


Figure P8.1

Participant H Trended Range Graph for VAS Body Awareness

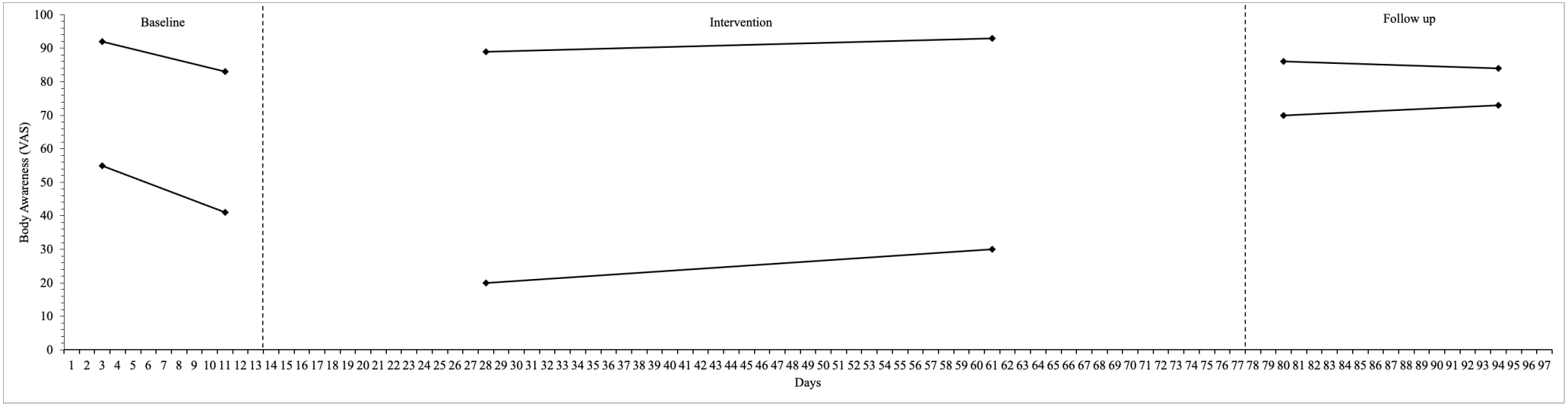


Figure P8.2

Participant H Trended Range Graph for VAS Emotion Regulation

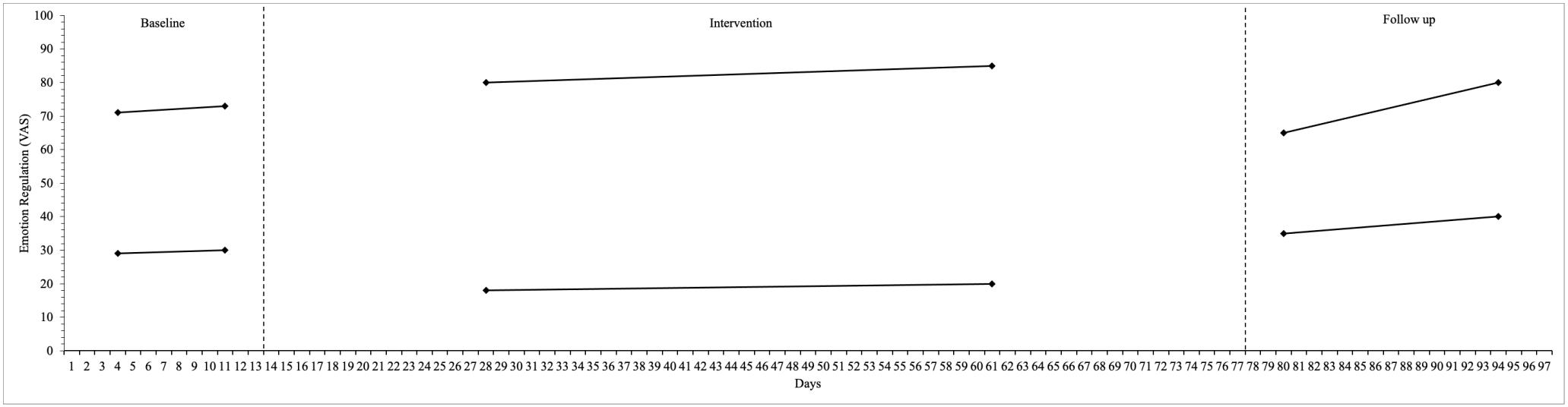


Figure P8.3

Participant H Trended Range Graph for VAS Chosen Behaviour

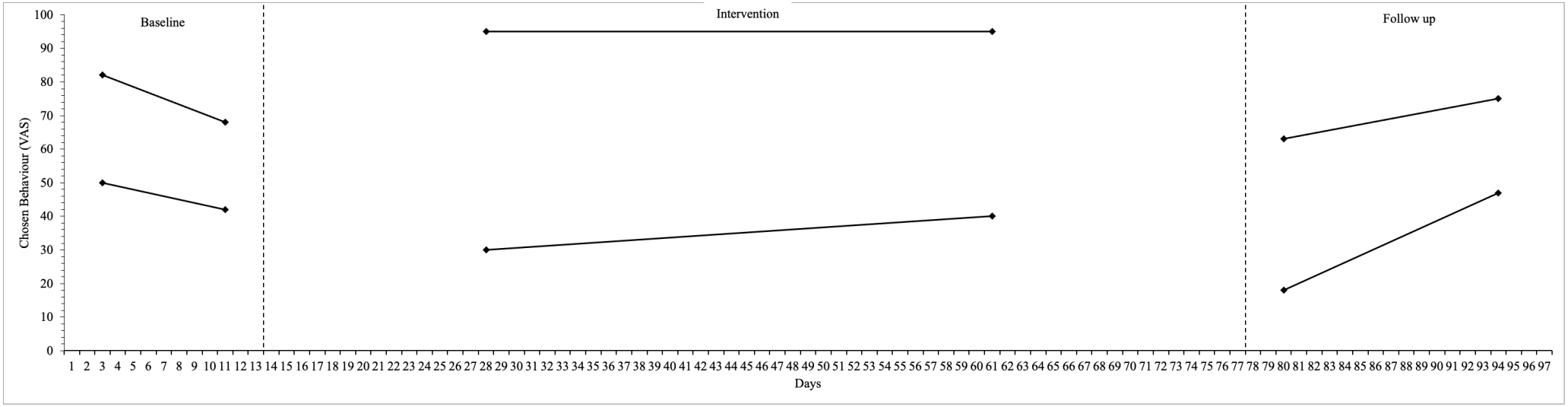


Figure P9.1

Participant I Trended Range Graph for VAS Body Awareness

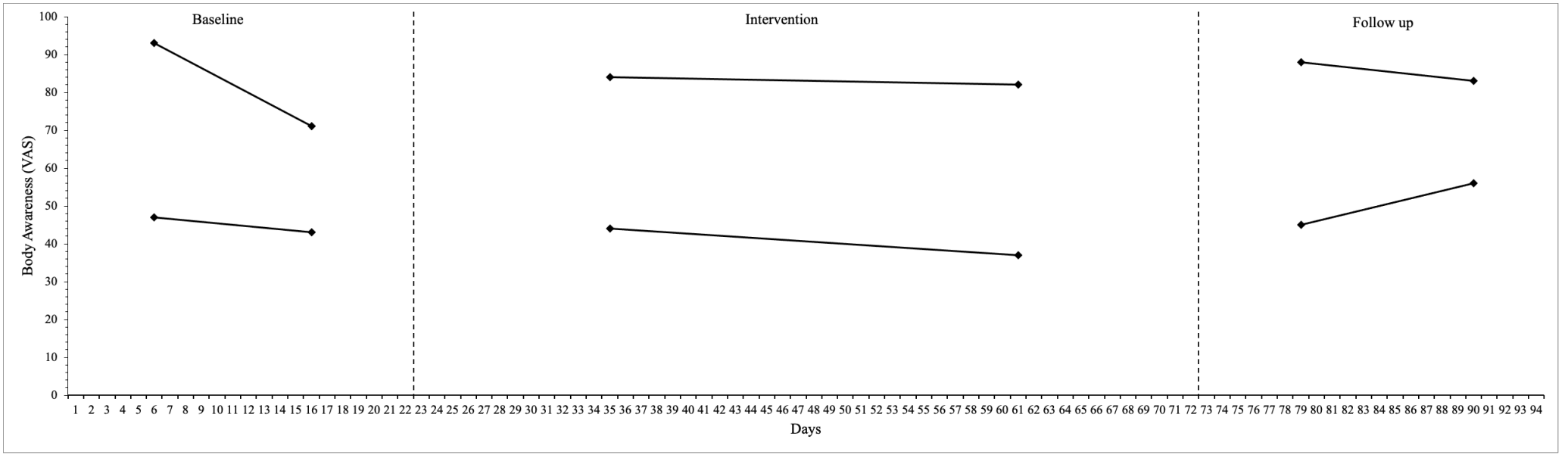


Figure P9.2

Participant I Trended Range Graph for VAS Emotion Regulation

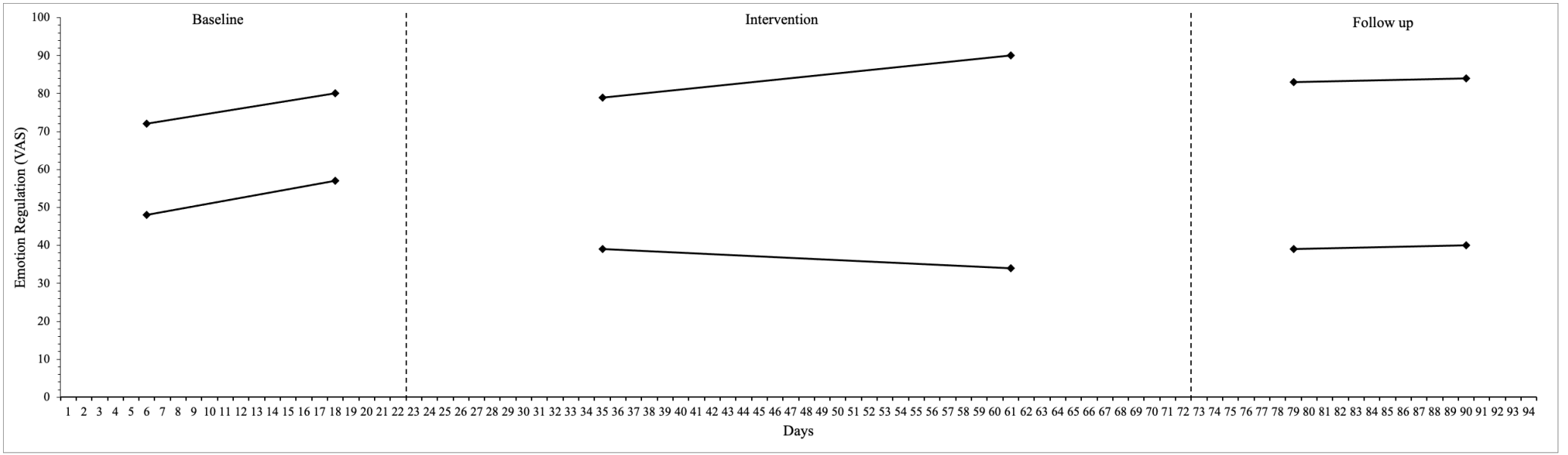


Figure P9.3

Participant I Trended Range Graph for VAS Chosen Behaviour

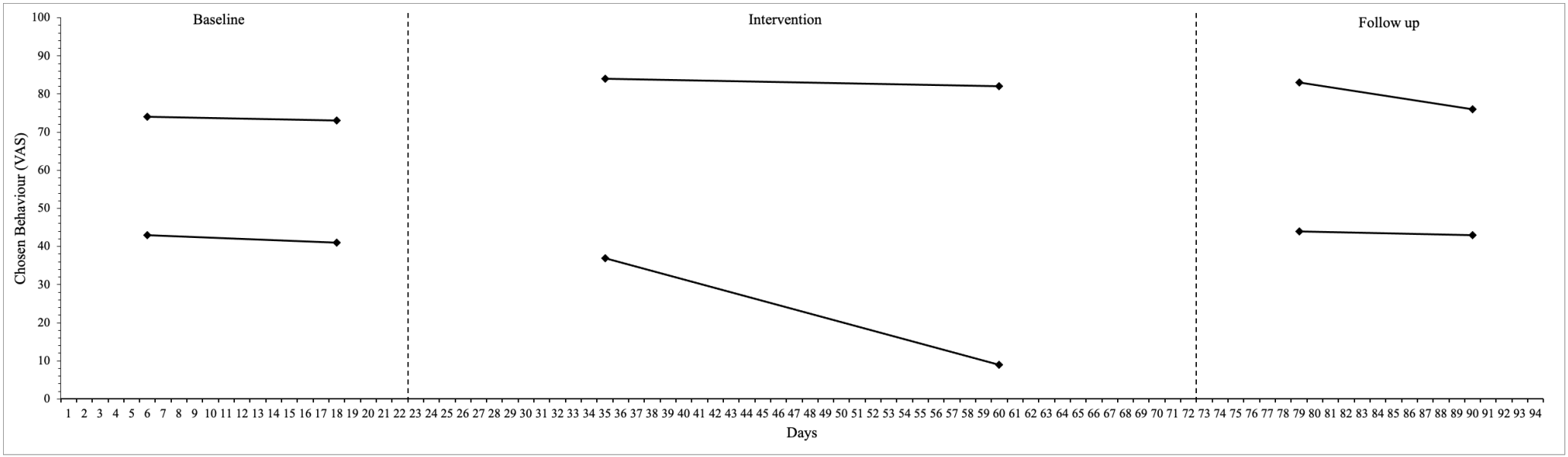
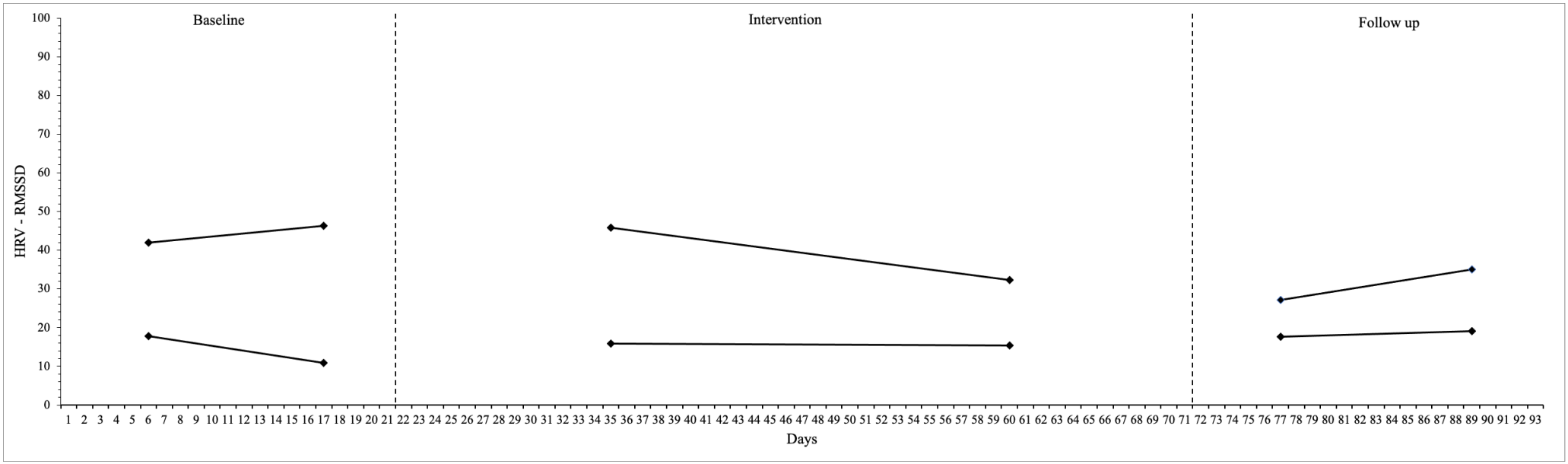


Figure P9.4

Participant I Trended Range Graph for HRV - RMSSD



Appendix Q

Summary of ACE Questionnaire Results

Table Q1

ACE Questionnaire scores

Participant	ACE Score
A	8
B	4
C	1
D	4
E	8
F	3
G	2
H	3
I	1

Note. ACE = Adverse Childhood Experience

Appendix R

Summary of Tau-U Data

Table R1

Tau-U Analyses

Participant	Measure	Comparison	Tau	SD Tau	P value	90% CI
A	Body Awareness	A x B	0.11	0.18	0.52	-0.18<>0.41
		B x C	0.52	0.20	0.01*	0.19<>0.85
		A x (B+C)	0.22	0.17	0.19	-0.06<>0.50
	Emotion Regulation	A x B	0.44~	0.18	0.01*	0.15<>0.73
		B x C	0.45	0.20	0.02*	0.12<>0.79
		A x (B+C)	0.53	0.17	<.001***	0.25<>0.81
	Chosen behaviour	A x B	-0.42	0.18	0.02*	-0.71<>-0.13
		B x C	-0.77	0.20	<.001***	-1<>-0.44
		A x (B+C)	-0.53	0.17	<.001***	-0.81<>-0.26
	HRV - RMSSD	A x B	-0.11	0.20	0.60	-0.44<>0.23
		B x C	0.05	0.22	0.82	-0.30<>0.40
		A x (B+C)	-0.08	0.19	0.67	-0.40<>0.23
B	Body Awareness	A x B	-0.29~	0.20	0.16	-0.62<>0.05
		B x C	0.77	0.25	<.001***	0.36<>1
		A x (B+C)	-0.21	0.20	0.29	-0.53<>0.12
	Emotion Regulation	A x B	-0.65	0.21	<.01**	-0.99<>-0.30
		B x C	0.85	0.25	<.001***	0.44<>1
		A x (B+C)	-0.48	0.20	0.02*	-0.82<>-0.14
	Chosen behaviour	A x B	0.38	0.19	0.05*	0.07<>0.70
		B x C	-0.34	0.25	0.17	-0.74<>0.07

		A x (B+C)	0.33	0.18	0.07	0.03<>0.64
	HRV - RMSSD	A x B	-0.22	0.23	0.34	-0.59<>0.16
		B x C	0.04	0.32	0.90	-0.48<>0.56
		A x (B+C)	-0.21	0.22	0.35	-0.58<>0.16
C	Body Awareness	A x B	-0.28	0.21	0.18	-0.62<>0.06
		B x C	-0.43	0.36	0.23	-1<>0.16
		A x (B+C)	-0.31	0.21	0.13	-0.65<>0.02
	Emotion Regulation	A x B	0.21	0.21	0.30	-0.13<>0.56
		B x C	0.02	0.36	0.95	-0.56<>0.61
		A x (B+C)	0.21	0.20	0.30	-0.12<>0.55
	Chosen behaviour	A x B	-0.73	0.21	<.001***	-1<>-0.39
		B x C	-0.29	0.36	0.42	-0.87<>0.3
		A x (B+C)	-0.73	0.21	<.001***	-1<>-0.39
	HRV - RMSSD	A x B	-0.20	0.22	0.37	-0.56<>0.16
D	Body Awareness	A x B	-0.77~	0.17	<.001***	-1<>-0.50
	Emotion Regulation	A x B	-0.82~	0.17	<.001***	-1<>-0.55
	Chosen behaviour	A x B	-0.96~	0.17	<.001***	-1<>-0.68
	HRV - RMSSD	A x B	-0.46	0.20	0.02*	-0.80<>-0.12
E	Body Awareness	A x B	0.95~	0.26	<.001***	0.53<>1
		B x C	0.74	0.17	<.001***	0.46<>1
		A x (B+C)	0.97	0.25	<.001***	0.554<>1
	Emotion Regulation	A x B	0.88	0.26	<.001***	0.46<>1
		B x C	-0.90	0.17	<.001***	-1<>-0.62
		A x (B+C)	0.61	0.25	0.02*	0.20<>1

	Chosen behaviour	A x B	0.24	0.26	0.34	-0.18<>0.67
		B x C	-0.23	0.18	0.20	-0.521<>0.07
		A x (B+C)	0.19	0.25	0.46	-0.22<>0.60
	HRV - RMSSD	A x B	-0.17	0.36	0.63	-0.77<>0.42
		B x C	-0.41	0.20	0.04*	-0.74<>-0.08
		A x (B+C)	-0.37	0.35	0.29	-0.95<>0.20
F	Body Awareness	A x B	0.5	0.20	0.01**	0.18<>0.82
		B x C	0.27	0.20	0.16	-0.05<>0.60
		A x (B+C)	0.54	0.19	<.01**	0.23<>0.86
	Emotion Regulation	A x B	0.46	0.20	0.02*	0.14<>0.79
		B x C	-0.26	0.20	0.19	-0.58<>0.06
		A x (B+C)	0.43	0.19	0.03*	0.11<>0.74
	Chosen behaviour	A x B	-0.36	0.20	0.07	-0.68<>-0.04
		B x C	0.21	0.20	0.30	-0.12<>0.53
		A x (B+C)	-0.32	0.19	0.09	-0.64<>-0.005
	HRV - RMSSD	A x B	0.09	0.23	0.70	-0.28<>0.46
		B x C	-0.09	0.26	0.74	-0.52<>0.35
		A x (B+C)	0.04	0.22	0.87	-0.32<>0.40
G	Body Awareness	A x B	0.15	0.26	0.56	-0.27<>0.57
		B x C	0.52	0.17	<.001**	0.236<>0.80
		A x (B+C)	0.33	0.25	0.19	-0.08<>0.74
	Emotion Regulation	A x B	-0.14	0.26	0.57	-0.57<>0.28
		B x C	0.11	0.17	0.54	-0.17<>0.39
		A x (B+C)	-0.10	0.25	0.68	-0.52<>0.31
	Chosen behaviour	A x B	-0.59	0.26	0.02*	-1<>-0.16

		B x C	-0.51	0.24	0.03*	-0.91<>-0.11
		A x (B+C)	-0.65	0.25	0.01**	-1<>-0.23
	HRV - RMSSD	A x B	-0.11	0.37	0.76	-0.72<>0.50
		B x C	-0.02	0.23	0.92	-0.40<>0.36
		A x (B+C)	-0.05	0.36	0.89	-0.63<>0.54
H	Body Awareness	A x B	0.07	0.19	0.71	-0.24<>0.37
		B x C	0.39	0.18	0.03*	0.09<>0.68
		A x (B+C)	0.15	0.18	0.43	-0.16<>0.45
	Emotion Regulation	A x B	0.03	0.19	0.89	-0.28<>0.33
		B x C	0.23	0.18	0.19	-0.06<>0.53
		A x (B+C)	0.08	0.18	0.68	-0.22<>0.38
	Chosen behaviour	A x B	0.33~	0.19	0.07	0.03<>0.64
		B x C	-0.39	0.18	0.03*	-0.69<>-0.10
		A x (B+C)	0.24	0.18	0.19	-0.06<>0.54
I	Body Awareness	A x B	0.57~	0.15	<.001***	0.32<>0.83
		B x C	-0.01	0.15	0.9262	-0.27<>0.24
		A x (B+C)	0.53	0.15	<.001***	0.29<>0.78
	Emotion Regulation	A x B	0.42	0.15	0.01**	0.16<>0.67
		B x C	-0.004	0.15	0.98	-0.26<>0.25
		A x (B+C)	0.38	0.15	0.01**	0.14<>0.62
	Chosen behaviour	A x B	-0.34	0.15	0.03*	-0.59<>-0.09
		B x C	0.26	0.15	0.10	0.001<>0.51
		A x (B+C)	-0.25	0.15	0.09	-0.49<>-0.01
	HRV - RMSSD	A x B	-0.25	0.15	0.11	-0.50<>0.01
		B x C	-0.10	0.15	0.52	-0.35<>0.15

	A x (B+C)	-0.27	0.15	0.06	-0.52<>-0.03

Note. A= Baseline phase; B = Intervention phase, C = Follow up phase; SD = Standard deviation; CI = Confidence interval; *=p<.05; **p<.01; ***p<.001~ = baseline trend corrected.

Table R2

Summary of Tau-U Statistical Change in Idiographic Measures

Idiographic Measure	Phase Contrast	Significant improvement (participant)	No significant change (participant)	Significant deterioration
Body awareness	A x B	4 (PtD, PtE, PtF, PtI)	5 (PtA, PtB, PtC, PtG, PtH)	0
	B x C	5 (PtA, PtB, PtE, PtG, PtH)	3 (PtC, PtF, PtI)	0
	A x (B+C)	3 (PtE, PtF, PtI)	5 (PtA, PtB, PtC, PtG, PtH)	0
Emotion regulation	A x B	5 (PtA, PtD, PtE, PtF, PtI)	4 (PtB, PtC, PtG, PtH)	1 (PtB)
	B x C	3 (PtA, PtB, PtE)	5 (PtC, PtF, PtG, PtH, PtI)	0
	A x (B+C)	4 (PtA, PtE, PtF, PtI)	4 (PtB, PtC, PtG, PtH)	1 (PtB)
Chosen behaviour	A x B	4 (PtA, PtC, PtD, PtG)	5 (PtB, PtE, PtF, PtH, PtI)	1 (PtB)
	B x C	3 (PtA, PtG, PtH)	5 (PtB, PtC, PtE, PtF, PtI)	0
	A x (B+C)	3 (PtA, PtC, PtG)	5 (PtB, PtE, PtF, PtH, PtI)	0
HRV	A x B	0	8 (PtA, PtB, PtC, PtE, PtF, PtG, PtH, PtI)	1 (PtD)
	B x C	0	8 (PtA, PtB, PtC, PtD, PtF, PtG, PtH, PtI)	1 (PtE)
	A x (B+C)	0	9 (PtA, PtB, PtC, PtD, PtE, PtF, PtG, PtH, PtI)	0

Note. A= Baseline phase; B = Intervention phase, C = Follow up phase; Pt = participant.

Table R3

Omnibus Effects: Weighted Averages of Data Non-overlap Between Phases

Idiographic Measure	Phase Contrast	Tau	P value	95% CI
Body awareness	A x B	0.09	0.19	-0.04<>0.22
	B x C	0.14	0.07	-0.01<>0.29
	A x (B+C)	0.27	<0.001***	0.12<>0.41
Emotion regulation	A x B	0.07	0.28	-0.06<>0.21
	B x C	0.01	0.94	-0.15<>0.16
	A x (B+C)	0.19	0.01**	0.05<>0.34
Chosen behaviour	A x B	-0.34	<0.001***	-0.47<>-0.20
	B x C	-0.04	0.58	-0.20<>0.11
	A x (B+C)	-0.27	<0.001***	-0.41<>-0.13
HRV	A x B	-0.19	0.04*	-0.37<>-0.01
	B x C	-0.04	0.68	-0.23<>0.15
	A x (B+C)	-0.16	0.13	-0.37<>0.05

Note. A= Baseline phase; B = Intervention phase, C = Follow up phase; SD = Standard deviation; CI = Confidence interval; *=p<.05; **p<.01; ***p<.001.

Appendix S

Summary of Raw Scores for Standardised Measures

Table S1

Raw Scores for MAIA-2

Pt	Item	Baseline (average)	Intervention							Follow up	
A	Noticing	1.83	0.75	1.25	2.00	2.75	2.75	3.75 [RC]		3.50 [RC]	3.75 [RC]
	Not-Distracting	1.33	0.33	1.00	0.83	1.00	0.50	1.50		1.17	1.33
	Not-Worrying	3.47	4.20	3.40	4.40	4.20	4.20	4.40		4.60	4.60
	Attention Regulation	1.10	1.00	1.43	1.43	2.00	1.86	3.14 [RC]		3.29[RC]	2.14
	Emotional Awareness	0.87	1.00	2.20	2.80 [RC]	2.60	3.00 [RC]	4.00 [RC]		3.80[RC]	3.40 [RC]
	Self-Regulation	1.83	1.00	1.50	2.25	3.50 [RC]	4.25 [RC]	3.75 [RC]		3.75 [RC]	3.00
	Body Listening	0.33	0.00	0.00	0.67	1.00	2.33 [RC]	3.00 [RC]		3.00 [RC]	3.33 [RC]
	Trusting	1.00	0.67	1.33	0.33	1.00	0.00	2.00		2.33 [RC]	3.33 [RC]
B	Noticing	2.08	1.00	0.50	0.75	1.00	0.75	2.50	2.50	0.75	
	Not-Distracting	2.06	2.17	2.00	1.67	1.83	1.83	2.17	2.33	2.67	
	Not-Worrying	1.00	0.20	0.40	1.00	1.00	1.40	1.20	2.40	1.40	
	Attention Regulation	0.67	0.71	0.29	0.86	1.86 [RC]	1.71	1.86 [RC]	2.00 [RC]	1.14	
	Emotional Awareness	1.53	0.80	0.60	1.60	1.00	1.40	1.80	2.20	1.00	
	Self-Regulation	0.67	0.25	0.50	1.00	1.00	1.25	1.50	2.50 [RC]	1.25	
	Body Listening	0.00	0.00	0.67	0.33	1.00	0.33	1.33	2.67 [RC]	1.00	
	Trusting	0.00	0.00	0.00	0.67	0.67	0.00	0.33	1.00	0.33	
C	Noticing	2.13	2.75	2.50	2.50	2.00	2.25			2.50	2.25
	Not-Distracting	2.75	2.33	3.17	2.33	3.67	2.67			2.17	2.83

	Not-Worrying	3.00	3.20	3.20	2.80	2.40	3.40		2.80	2.60		
	Attention Regulation	1.43	1.29	1.86	1.71	1.14	1.43		1.57	1.29		
	Emotional Awareness	2.50	2.60	2.40	2.60	2.00	2.60		2.20	2.00		
	Self-Regulation	1.88	1.50	1.75	1.75	1.50	1.75		1.75	2.25		
	Body Listening	1.83	2.00	1.00	1.00	1.33	1.33		2.33	1.67		
	Trusting	0.83	0.67	0.67	0.33	0.33	0.67		0.33	0.67		
D	Noticing	4.42	3.75	4.75	4.00	1.00[D]	2.25[D]					
	Not-Distracting	2.11	2.00	2.33	2.17	1.83	1.50					
	Not-Worrying	2.20	2.40	2.40	2.20	4.00[RC]	2.40					
	Attention Regulation	3.33	2.57	2.57	3.86	3.57	3.43					
	Emotional Awareness	4.47	4.60	3.20	4.00	4.80	4.20					
	Self-Regulation	2.75	3.00	4.00	4.00	4.00	3.25					
	Body Listening	3.00	3.33	3.33	4.00	4.00	3.67					
	Trusting	2.56	3.33	3.33	4.00[RC]	3.33	3.67					
E	Noticing	3.00	2.25	3.00	3.75	4.00			4.00	4.50[RC]	5.00[RC]	
	Not-Distracting	0.50	1.00	1.33	3.00[RC]	3.00[RC]			4.17[RC]	4.17[RC]	4.67[RC]	
	Not-Worrying	1.60	2.60	2.40	2.40	3.20[RC]			2.60	2.20	4.40[RC]	
	Attention Regulation	2.14	1.29	3.00	4.00[RC]	3.86[RC]			5.00[RC]	5.00[RC]	5.00[RC]	
	Emotional Awareness	4.40	3.80	3.40	4.00	4.00			5.00	5.00	5.00	
	Self-Regulation	3.25	2.00	2.75	4.00	4.00			4.50	5.00[RC]	5.00[RC]	
	Body Listening	2.00	2.00	2.67	4.00[RC]	4.00[RC]			4.33[RC]	5.00[RC]	5.00[RC]	
	Trusting	1.33	2.00	3.00[RC]	3.33[RC]	4.00[RC]			4.67[RC]	5.00[RC]	5.00[RC]	
F	Noticing	3.75	4.00	3.75	4.50	4.75	4.00	4.50	4.00	4.25	4.00	3.50
	Not-Distracting	1.00	1.17	1.33	1.83	2.33[RC]	1.17	1.00	1.00	1.17	1.17	1.00
	Not-Worrying	1.40	1.40	1.00	1.40	1.80	1.00	1.80	1.60	1.60	1.20	1.80
	Attention Regulation	2.00	2.86	2.71	2.14	2.86	2.14	1.86	2.14	2.14	2.14	2.71
	Emotional Awareness	3.70	4.20	3.60	3.60	4.00	3.40	2.80	3.40	3.20	3.00	3.40

	Self-Regulation	2.13	2.75	2.75	2.75	3.50 RC	2.75	2.25				2.50	2.25	2.25	2.75
	Body Listening	1.67	2.67	3.33 RC	2.33	4.00 RC	2.00	2.00				2.33	3.00	3.00	2.67
	Trusting	0.33	2.00 RC	1.00	1.00	3.00 RC	2.00 RC	1.00				1.00	3.00 RC	2.33 RC	2.67 RC
G	Noticing	3.00	4.00	3.50	4.00	3.75	3.50	4.25	4.00	4.25		4.50 RC	4.75 RC	4.50 RC	
	Not-Distracting	1.17	0.67	0.83	0.83	1.50	1.33	1.67	1.50	1.33		1.00	0.50	1.50	
	Not-Worrying	2.80	3.00	3.40	3.00	2.80	2.80	3.20	3.40	3.40		3.80	4.60 RC	4.00	
	Attention Regulation	2.86	2.86	2.57	2.29	2.43	2.57	3.00	2.57	3.14		3.29	4.14 RC	3.43	
	Emotional Awareness	4.60	3.60	4.00	4.00	3.75	4.00	4.40	3.80	4.20		4.60	5.00	4.60	
	Self-Regulation	3.25	2.25	3.50	2.50	3.00	3.00	3.00	3.25	3.50		3.75	3.75	3.50	
	Body Listening	3.00	2.67	3.00	2.33	2.33	3.50	2.67	3.33	3.33		4.67 RC	4.33	3.67	
	Trusting	3.00	2.33	2.33	2.33	3.00	3.33	2.67	3.33	3.33		4.00	4.33 RC	4.00	
H	Noticing	2.13	2.75	3.00	2.50	3.75 RC	3.25	4.00 RC	4.25 RC	4.25 RC	4.25 RC	4.50 RC		4.50 RC	4.75 RC	4.75 RC
	Not-Distracting	0.67	1.00	0.33	1.00	1.17	0.83	0.83	0.67	0.50	0.67	0.50		0.50	0.17	0.33
	Not-Worrying	3.20	2.60	2.20	2.80	3.00	2.60	2.60	2.80	2.80	2.40	2.80		2.00	2.40	2.40
	Attention Regulation	2.29	1.29	2.43	2.14	2.71	2.29	2.43	3.00	3.00	3.00	3.14		3.29	3.71 RC	3.00
	Emotional Awareness	4.00	3.80	4.40	4.20	4.20	4.20	4.80	5.00	5.00	5.00	4.80		5.00	5.00	5.00
	Self-Regulation	2.00	2.00	3.00	2.25	3.25	3.25	3.50 RC	2.50	3.50 RC	3.75 RC	3.75 RC		3.00	4.50 RC	3.75 RC
	Body Listening	1.50	1.67	3.00 RC	2.00	2.67	2.00	3.00 RC	3.00 RC	3.33 RC	2.67	3.00 RC		3.00 RC	3.67 RC	3.00 RC
	Trusting	2.17	3.00	3.00	3.00	3.33	4.00 RC	3.33	3.00	3.33	3.33	3.33		3.33	4.00 RC	4.33 RC
I	Noticing	2.06	2.50	2.50	2.25	2.00	1.75	1.75	2.00			1.75	2.00	1.75		
	Not-Distracting	2.38	2.83	1.33	1.50	0.83	1.50	1.50	1.67			2.50	2.50	2.00		
	Not-Worrying	3.05	4.20	4.00	4.00	4.60 RC	4.20	4.40	4.40			4.80 RC	4.80 RC	4.40		
	Attention Regulation	0.57	0.71	1.14	0.71	1.57	1.71 RC	1.71 RC	2.43 RC			3.00 RC	0.86	1.71 RC		
	Emotional Awareness	1.95	3.00	2.20	2.00	1.40	2.00	2.80	2.60			2.40	2.20	1.40		
	Self-Regulation	0.50	1.75	2.75 RC	2.50 RC	1.75	1.75	2.50 RC	3.25 RC			3.50 RC	1.50	2.25 RC		
	Body Listening	0.33	0.33	0.67	0.67	1.00	0.67	0.67	1.67			1.00	0.67	2.00 RC		
	Trusting	2.75	3.00	1.00D	4.00	2.00	0.67D	1.67	1.00D			1.33D	0.67D	0.67D		

Note. MAIA-2 = Multidimensional Assessment of Interoceptive Awareness, Version 2 – 37 items (range: 0-5); Pt = participant; [RC] = reliable change; [D] = reliable deterioration indicated by Jacobsen & Traux (1991).

Table S2

Raw Total Scores for FFMQ-15

P	Baseline				Intervention									Follow up			
1	29	32	39		34	29	34	41	43	51[RC]				48 [RC]	46 [RC]		
3	28	35	30		29	40	37	35	31	35	36	39					
4	42	43			45	42	40	42	40					40	41		
5	40	47	48		43	47	47	44	46								
6	39				27	50	46	57 [RC]						68 [RC]	73 [RC]	69 [RC]	
7	34	34			42	40	44	45	46	41				43	47 [RC]	46 [RC]	44 [RC]
8	47				49	50	46	47	48	52	52	52		57	56	54	
10	56	43	54		54	56	58	59	57	58	55	61	59	63 [RC]	63 [RC]	61 [RC]	
11	41	48	48	54	53	46	39	49	46	45	52			50	45	46	

Note. FFMQ-15 = Five Facet Mindfulness Question – 15 items (range: 15-75); [RC] = reliable change indicated by Jacobsen & Traux (1991).

Table S3

Raw Total Scores for DERS

P	Baseline					Intervention								Follow up		
1	61	42	36		47	57	60	46	45	18				12	12	
3	86	102	107			95		76	91	99	91	91	92			
4	25	26			36	32	27	22	28					37	31	
5	-44	-12	-9		-52	-13	-4	-20	-13							
6	63				79	20 CSC	2 CSC	-17CSC						-23 CSC	-18 CSC	-29 CSC
7	95	75			56	81	44	25	43	41				67	50	47
8	15				20	19	19	21	15	12	6	5		-3	-8	3
10	-7	-14			-22	-31	-15	-51 CSC	-28	-29	-41	-40	-52 CSC	-64 CSC	-64 CSC	-35	-68CSC
11	36	20	9	-2	3	5	-6	5	4	16	0				9	15	11

Note. DERS = Difficulties in Emotion Regulation (range: -180-180); RC = reliable change; CSC = clinically significant change indicated by Jacobsen & Traux (1991).

Appendix T

Qualitative Feedback on Acceptability

Table T1

Qualitative Feedback on Acceptability

	Comments
Feedback 1	
Q1	The sunrise new horizons technique where you have the ability to focus on your breathing close your eyes, smile and start again. The ability to self soothe with the rocking and focused breathing. Sucking of mints. This has helped me no end significantly impacting my anxiety.
Q2	Firstly it opened my eyes to secret eating. It empowered me to face why I was eating and the reality that it compounds the issue rather than soothing it I think this poly a gal therapy is impactful on me as a comfort eater because it trains us how to sit with the compelling emotions without the need to bury them in food. It's a technique that empowered me to recognise that I can eat just enough to satisfy my hunger because as an adult, I know I will have my next meal. I can slow down my eating and enjoy my food instead of hoovering food into the abyss of flawed thinking. I can understand that when I feel emotional distress I can evoke the vagaries nervous system by sucking on a mint, embrace the new horizon whilst soothing myself without the need to eat. Ironically this therapy has also had an impact on my choices around food. I can now eat to live rather than living to eat. This therapy was so o dramatically powerful because I believe that I was in the right place to hear and assimilate what I learned. The Batak nerve ladder was also a significant tool in teaching it's ok to traverse from top to bottom or bottom to top. When I first started I was always in the flight response mode but now I frequently dip into the green zone instead of sinking into the red repeatedly. Something I had previously been unaware of. Learning the stomach is connected to the brain was a brilliantly exposed detail of

which I had been blissfully unaware. There will be times where I slump low but I can simply give myself permission to simply start again with the new horizons technique. The turning of my frown to a smile whilst focused on my breathing whilst soothing myself by giving the inner child permission to feel safe and be soothed by the self hug and gentle rocking.
A residual benefit of this therapy was the impact focused breathing had on my asthma. The change was as significant as the difference between night and day.

I learned so much through this discourse- my only regret was that the window was so short as little time was afforded significant changes in routine practices. Longer sessions between each face to face sessions would have been beneficial. Whilst I will always have a weakness in the polvagal nerves the therapy was illuminating and helpful.

Feedback 2

Q1 Helpful: breathing techniques, assessment of surroundings, communication with people, eyebrow wag, physical exercise.
Unhelpful: chewing gum, plants

Q2 Reevaluation of state of self and emotions. Understanding my bodies needs. Characteristics of fight or flight. Modified my work/life imbalance to a more conscious focused attitude.

Feedback 3

Q1 Everything i found helpful. Learning the science behind the nervous system was so interesting and helpful to be able to understand it.

Q2 It has made me become more aware of myself, my feelings, my body. Its allowed me to be more accepting of me too. Ive stopped being my own worst enemy all the time

Feedback 4

Q1 I was very comfortable with Alex, she was very warm and caring. I was able to be very open and vulnerable with her. Polyvagal therapy was a unique approach to my mental health and I felt it provided breakthroughs that other forms of therapy haven't been able to.

Q2	It has increased my self awareness of my mental health, triggers and associated physical health. Made me understand myself in a unique and new way.
Feedback 5	
Q1	It was helpful to understand how my body naturally reacts to external factors and that reaction is not something I can control, I can just learn to recognise what the reaction is and adapt my actions to support what my body needs. It was helpful to be given techniques to use and to categorise them depending on which system was at the forefront. I like to know the why I am feeling the way I am or acting the way I am and the interventions did not help with that but I have learnt that the what is more important than the why!
Q2	I have learnt how to move myself out of flight or fight mode using the techniques I have identified that work for me - breathing, getting outside - and am starting to use techniques to move myself out of dorsal vagal if I need to but also realising that being in dorsal vagal is ok. I am now able to listen my body more to tell me what it needs although this will take continued practice.
Feedback 6	
Q1	Breathing Eyebrow wagging Learning techniques to move to the different zones, grey to green, and using red zone symptoms/feeiings in a positive way.
Q2	Helps me manage flight ir fright responses in a more moderate way.

Note. Q1 = Can you tell us, in your own words, what you found helpful and less helpful in relation to the intervention; Q2 = Can you tell us, in your own words, what difference, if any, the intervention has had on your day-to-day life. Quotes have been copied verbatim.