Transdiagnostic Mechanisms and Their Application in Therapeutic Interventions Targeting Negative Symptoms in Schizophrenia: A Systematic Review and Empirical Study.

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Use of AI Tools

Generative AI was used in the preparation of this thesis in accordance with the University of Glasgow's guidance on responsible AI use in academic work (https://www.gla.ac.uk/myglasgow/sld/ai/students/).

ChatGPT (OpenAI, GPT-4, accessed via https://chat.openai.com) was used to support the author's development of R programming skills, specifically for processing actigraphy data in the empirical project. The tool was provided with detailed instructions, which it translated into code using relevant R packages. The resulting scripts were reviewed, tested, and adapted as necessary. This iterative process facilitated the author's understanding and proficiency in R, and enabled the creation of reproducible coding pipelines essential for managing the large volume of data, comprising hundreds of thousands of data points, and for producing accurate, interpretable visual analyses.

ChatGPT was also used to support clarity of written expression across both the systematic review and empirical project, including assistance with grammar, phrasing, and overall readability. Outputs from the tool were reviewed and used to inform manual editing of the text, no AI-generated content was used in place of original analysis or interpretation.

Chapter 1: Systematic Review

Title: Does physical activity increase motivation in adults with schizophrenia? A systematic review.

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Plain Language Summary

People with schizophrenia often experience "negative symptoms" such as low motivation and reduced emotional expression. These symptoms can make it difficult to work, socialise, or enjoy everyday activities, and they often lead to a lower quality of life. Unfortunately, current treatments do not work very well for these kinds of symptoms.

One area of interest is whether exercise might help. Some research suggests that taking part in physical activity could improve motivation, help build healthy habits, and increase confidence. However, it is not yet clear whether people need to feel motivated before they can benefit from exercise, or if exercise itself can help boost motivation. This review looked at research studies that explored the effect of exercise on motivation in people with schizophrenia.

We searched three major research databases for relevant studies. To be included, studies had to use exercise-based programmes lasting at least three weeks and report on motivation as an outcome. Out of 2,700 studies screened, six met all the criteria. We carefully reviewed these studies and assessed their quality.

The results were mixed. Some studies showed that exercise helped improve motivation, especially when motivation was measured by trained observers. Other studies found no clear benefit. Overall, the review suggests that exercise may help some people with schizophrenia feel more motivated, but more high-quality research is needed. Future studies should use better ways to measure motivation and explore how exercise might support people to stay engaged in everyday life.

Abstract

Negative symptoms of schizophrenia, including diminished motivation and reduced expressiveness, severely affect occupational, social, and recreational functioning, as well as quality of life. Despite these impacts, treatment options remain limited, with pharmacological and psychological interventions providing only modest improvements. Recent research suggests that motivational enhancement is central to reducing negative symptoms. Exercise has demonstrated small but significant positive effects, potentially by fostering motivation, improving self-efficacy, and promoting habit formation. However, the direction of this effect remains unclear; motivation may be a prerequisite for engagement in goal-directed behaviour such as exercise, highlighting the need for further investigation.

This review was registered on PROSPERO (CRD42024592533) on 15 October 2024. Randomised controlled trials published in English since 2010 were included if they examined exercise-based interventions (≥3 weeks, ≥8 hours total) in individuals with schizophrenia or psychosis NOS, and assessed motivation as an outcome. Studies using recognised therapeutic modalities or mind-body exercises were excluded. A systematic search of Medline, Embase, and PsycINFO identified 2,700 records; 95 full texts were reviewed, with 6 meeting inclusion criteria. A second reviewer assessed 10 full texts and all included studies for quality appraisal. No additional studies were found through citation searching.

Exercise interventions showed mixed effects on motivation. Larger, higher-quality studies using observer-rated measures tended to find improvements, particularly in general motivation. These findings suggest that exercise may support motivational enhancement. However, measurement limitations and methodological variability highlight the need for further research to clarify mechanisms of change.

1.0 Introduction

The negative symptoms of schizophrenia are a cluster of deficits in emotional expression, motivation, and social functioning that significantly impact daily life. Negative symptoms are characterised by diminished experiences: blunted affect, anhedonia, avolition, asociality, and alogia.

These symptoms have substantial functional consequences, significantly limiting engagement in daily life, the ability to maintain relationships, and progress towards personal or occupational goals (Fervaha, Foussias, Agid, & Remington, 2014). Collectively, these overlapping difficulties contribute to reduced independence, poorer quality of life, and increased reliance on carers or support services (Fervaha et al., 2014).

Treatment for negative symptoms is often of limited efficacy. Pharmacological interventions, highly effective in addressing positive symptoms, have at best modest benefits for negative symptoms (Arango, Garibaldi, & Marder, 2013). Psychological interventions are varied in content and structure but again are only associated with modest positive effects on negative symptomology, while being lengthy and costly (Lutgens, Gariepy, & Malla, 2017).

The limited efficacy of interventions for negative symptoms could be a result of an incomplete understanding of mechanistic treatment targets (McLeod, 2022). In negative symptoms, motivation has become one such key mechanistic target; as it has been shown to be strongly associated with functional outcomes (Foussias et al., 2011) and improvements have been shown to have a cascading beneficial impact on the surrounding network of symptoms (James et al., 2024; Strauss et al., 2020). It is therefore important to investigate existing interventions and their impact on this identified treatment target.

Physical activity and exercise are among the most effective ways to enhance mental health and well-being (Stubbs et al., 2018). Research has shown that regular physical activity can significantly reduce various forms of mental distress, including stress, anxiety, and depression (Schuch et al., 2016; Stubbs et al., 2017). Regular physical activity has been

associated with motivational benefits in healthy individuals, and a previous systematic review concluded that exercise has a significantly beneficial, if small (SMD = −0.20) effect on negative symptoms (Sabe, Kaiser, & Sentissi, 2020).

The process by which exercise may affect motivation in people with schizophrenia is not fully understood. In healthy individuals the reinforcing effects of physical activity is associated with the interaction of beneficial physiological (e.g. release of endorphins and dopamine which produces euphoric feelings), psychological (e.g. sense of achievement, improvement and mastery) and health (e.g. strength, fitness, increased longevity) factors.

In schizophrenia, dopamine dysregulation and impaired reward processing complicate this reinforcement cycle. While, antipsychotics often dampen dopamine activity (Howes & Kapur, 2009), exercise may enhance dopamine binding in regions such as the striatum, supporting motivation and pleasure (Fisher et al., 2013). It also activates other neurochemical systems, including endorphins and endocannabinoids, which independently promote mood and reduce stress (Basso & Suzuki, 2016; Heyman et al., 2012).

While dopamine dysregulation may disrupt one component of this reinforcement cycle, other positive aspects of exercise are still likely to confer benefits. Structured exercise can provide consistent health and psychological gains, as well as external reinforcements such as routine and social interaction, which may help compensate for intrinsic reward deficits and support improvements in motivation (Firth et al., 2016).

These motivational changes may be limited to exercise-specific contexts; for example, an increased willingness to engage in physical activity reinforced by the physiological pleasure and sense of well-being associated with regular structured activity. Alternatively, these gains may generalise across domains. In such cases, the experience of structured activity and associated pleasure may contribute to disconfirming defeatist beliefs and enhancing self-esteem, thereby creating a foundation for broader engagement in daily tasks and social activities.

The aim of this review is to evaluate evidence addressing these possibilities in people diagnosed with schizophrenia spectrum disorders.

1.1 Research questions

Main Research Question

Does participation in exercise interventions increase motivation in adults with schizophrenia?

Secondary Research Questions

1) Do exercise interventions increase generalised motivation in this population?
2) Do exercise interventions increase task-specific motivation to engage in physical activity?

2.0 Methods

2.1 Registration

On the 15th of October 2024 the protocol was published on the international prospective register of systematic reviews (Prospero; registration #: CRD42024592533). The protocol includes the aims, objectives, inclusion and exclusion criteria as well as planned analysis of quality and plans for data synthesis.

2.2 Eligibility Criteria

For the purposes of this review, exercise was defined as “a subset of physical activity that is planned, structured, repetitive, and purposive, with the aim of improving or maintaining one or more components of physical fitness” (Caspersen, Powell, & Christenson, 1985).

The present review’s eligibility criteria was developed in line with a previous review in the area (Sabe et al., 2020). An additional exclusion of publications since 2010 was added due to evidence that older generation antipsychotics are known confound the effects of exercise interventions (Rismayer, Kambeitz, Javelle, & Lichtenstein, 2024).

2.2.1 Inclusion Criteria

- Written in English.
- Published since 2010 in peer-reviewed journals.
- Randomised controlled trail design.
- Interventions that consist primarily of exercise.
- Minimum duration of three weeks and eight hours total practice.
- Participant group with a diagnosis of schizophrenia or psychosis not otherwise specified (NOS), as defined by standard diagnostic criteria such as the DSM-5 or ICD-10.
- Includes measure of motivation; including domain of established negative symptom measure, specific measure of motivation to exercise, and objective measures of physical activity.

2.2.2 Exclusion Criteria

- Intervention with content from recognised therapeutic modalities which could confound effect of exercise on motivation (e.g., Cognitive Behavioural Therapy, Motivational Interviewing, and Social Skills Training Interventions)
- Includes mind-body exercises (e.g. Yoga, Tai Chi).
- Includes any participants without a diagnosis of a schizophrenia spectrum disorder.

A search of Medline, Embase and PsycINFO was completed on the 14th of October 2024 by the primary author. Filters were applied for papers in English, since 2010 and for human subjects.

2.3 Data collection

2.3.1 Search strategy

Search syntax incorporated search terms relating to schizophrenia, exercise and motivation. Refinement of the syntax was supported by a University of Glasgow librarian. Where possible, previous systematic reviews or meta-analysis search terms were used (Clark, Maguire, Cannon, & Leung, 2021; Sabe et al., 2020). Minor changes to the syntax were made where appropriate. There were no available high-quality search strategies on the topic of motivation, so a bespoke search was developed. General terms around motivation and avolition were accompanied by specific motivational measures. The list of measures were sourced primarily from a relevant meta-analysis (Luther, Fischer, Firmin, & Salyers, 2019). The search terms were adapted for each of the databases listed previously (Please see Appendix B, p70-73 for full search terms).

2.3.2 Study Selection & Inclusion Decision Making

Papers will be uploaded to systematic review website Rayyan (Ouzzani, Hammady, Fedorowicz, & Elmagarmid, 2016). Titles and abstracts will be examined by primary reviewer (ZB). Full text papers will be examined by primary reviewer and 10 percent of these will be reviewed independently by a second reviewer (RW).

Forwards-backwards citation searching will be used to search for additional eligible papers.

2.4 Risk of Bias & Certainty Assessment

A risk of bias analysis was conducted using the Risk of Bias (2) (ROB2) tool (Sterne et al., 2019). Risk of bias is an essential component of systematic reviews for interventional studies. The analysis was completed independently by the author and the second reviewer using in-built guidance within the ROB2 macro, alongside published guidance from developers (Moore, Higgins, & Dwan, 2023). Discrepancies in scoring between the two reviewers were resolved through discussion.

Certainty of evidence was considered narratively within the synthesis and is qualitatively addressed in the Discussion section. Key elements commonly included in formal certainty

assessments, such as study quality, consistency of findings and applicability, are reflected upon throughout the review.

2.5 Synthesis & Analysis Approach

A narrative synthesis was conducted following well-established guidance (Popay et al., 2006). A narrative synthesis consists of four stages: theory development, developing a preliminary synthesis, exploring relationships and assessing the robustness of the synthesis.

This approach to analysis is justified by the heterogeneity in outcome measures, as well as the dose, structure, and format of exercise interventions, which preclude meta-analytic synthesis. Moreover, the structured approach of narrative synthesis supports the development of theoretical explanations and underlying mechanisms, which is particularly important when evaluating interventions not typically associated with the specific area of difficulty under investigation.

2.5.1 Theory Development

Engagement in physical activity among individuals with low motivation may occur through passive compliance or a general tendency to agree to structured routines (e.g., as part of a research study), rather than through self-initiated, goal-directed drive. Following this initial engagement, the experience of exercise itself, through mechanisms such as cognitive enhancement, goal completion, or social interaction, may lead to downstream improvements in motivation.

These motivational changes may be limited to exercise-specific contexts (task-specific motivation); for example, an increased willingness to engage in physical activity reinforced by the physiological pleasure and sense of well-being associated with regular structured activity, increased association with peers in this setting and an increased sense of competence as mastery in the exercise type increases. Within the framework of Self-Determination Theory (SDT) (Deci & Ryan, 2012), these processes may reflect enhanced

feelings of relatedness through social connection and competence through developing skills and mastery, both of which are central to fostering intrinsic motivation.

Alternatively, these gains may generalise across domains (generalised motivation). In such cases, the experience of structured activity and associated pleasure may contribute to disconfirming defeatist beliefs and enhancing self-esteem, thereby creating a foundation for broader engagement in daily tasks and social activities (Campellone, Sanchez, & Kring, 2016). These processes may also support autonomy, the third core component of Self-Determination Theory (SDT), by providing individuals with a sense of choice and control over their actions, which, in combination with enhanced competence and relatedness, can foster more sustained and self-determined forms of motivation.

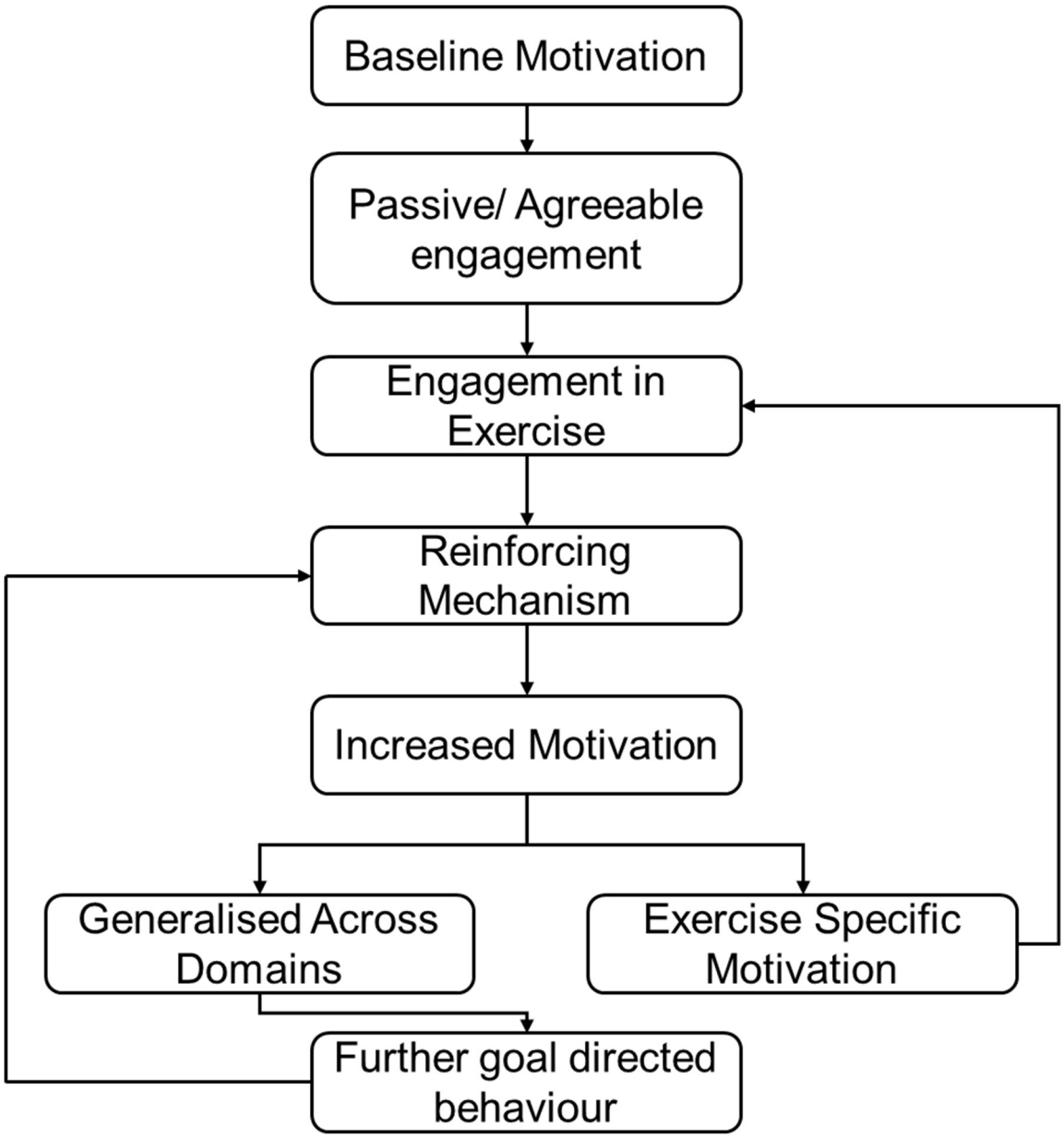


Figure 1. *Proposed Mechanism of Motivational Change via Exercise*

3.0 Results

3.1 Search Results

A search of Medline, Embase and PsycINFO was completed on the 14th of October 2024 by the primary author. Filters were applied for papers in English, since 2010 and for human subjects. The search yielded 2196 titles, of which 95 were selected for full-text review (see Figure 2). Ten percent of records (10) at this stage were randomly selected to be assessed

by a second reviewer (RW). In the case of disagreement, a third reviewer (HM) adjudicated. However, there was 100% agreement between the reviewers. Of the 95 records, six were eligible for inclusion. The search was re-run on the 27th of June 2025 to check for any additional results. There were an additional 199 results, but none met the criteria for full text review.

The main reasons for exclusion were due to research design (30) and publication as conference papers (29). The other exclusions were associated with measurement (10), intervention content (9), population (7) and other reasons (3). Overall, six studies were assessed as eligible for analysis.

3.2 Qualitative description of studies

The systematic review includes 6 studies (n= 307 patients). All studies investigated the use of structured exercise interventions among individuals with schizophrenia. The interventions varied in format, intensity, and duration (see Table 1). In some studies, the exercise was combined with psychoeducation, lifestyle counselling, components such as goal setting and discussion sessions.

Motivation was measured using a range of self-report measures, assessor rated measures and objective tools. Self-report measures included the International Physical Activity Questionnaire (IPAQ), the Behavioural Regulation in Exercise Questionnaire-2 (BREQ-2) and the Korean version of the Physical Activity Scale for the Elderly (K-PASE). The two assessor rated measures were the Scale for the Assessment of Negative Symptoms (SANS) and the Schizophrenic Quality of Life Scale (SQLS). Objective recording of physical activity was captured by pedometers of various types.

Figure 2. *Prisma Flow diagram (Haddaway, Page, Pritchard, & McGuinness, 2022)*

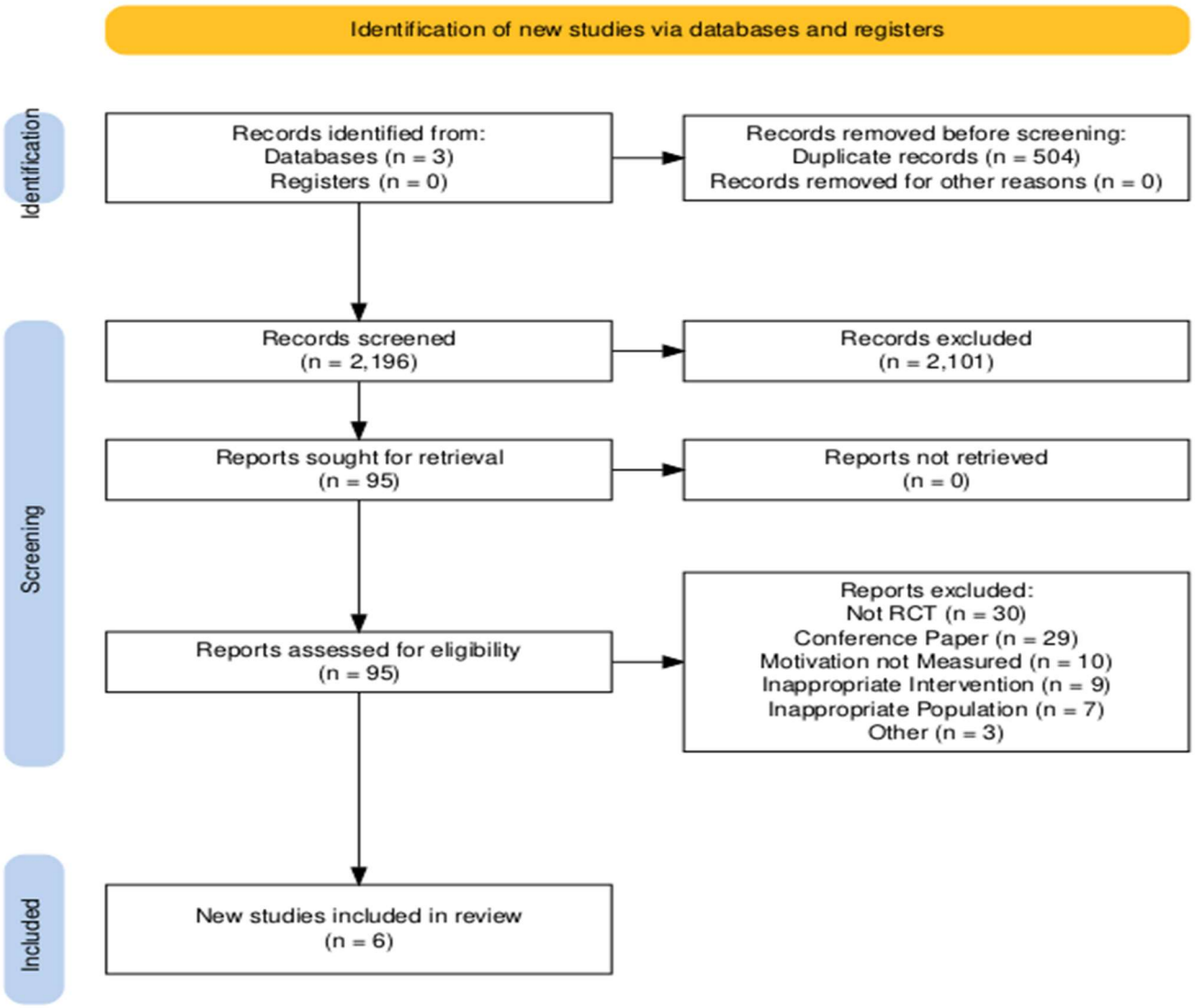


Table 1 *Descriptive and Methodological Characteristics of Included Studies*

Authors and publication year	Country	Participants	Assessment tools	Frequency of measurement	Exercise Modality	Description of control	Exercise Intensity	Exercise Dose (minutes)
Andersen et al., 2020	Norway	Enrolled = 82 Analysed = 47 Females = 32 (39%) Males = 50 (61%) Age ≈ 36.5 years	Pedometer	Twice (Pre & Post)	High intensity interval training	Computer gaming skills group	4x4 minute at 85-95% maximum heart rate, then 3 min of walking at 70% heart rate, then 5-minute cool-down	Session: 45 Twice per week for 12 weeks Weekly: 90 Total: 1080
Areshtanab et al., 2020	Iran	Enrolled = 68 Analysed = 68 Males = 68 (100%) Females = 0 (0%) Age ≈ 32.81	SQLS (Motivation & Energy Domain)	Twice (Pre & Post)	Running and stretching	Fresh air, fun and games without programmed activity	Running at 65% heart rate for 12 minutes in week 1, raised to 80% heart rate in week 8	Session: 20-40 Three times per week for 8 weeks Weekly: 90 Total: 720
Dunleavy et al., 2024*	UK	Enrolled = 17 Analysed = 15 Males = 15 (100%) Females = 0 (0%) Mean Age = 26.67 years	Pedometer IPAQ	Twice (Pre & Post)	Mixed aerobic activities including game participation	Treatment as usual (TAU); not otherwise described	Exercise sessions targeted at 60-75% of an individual's maximum heart Gradual rate	Session: 60 Two to three times per week for 6 weeks Weekly: 150 Total: 900

Authors and publication year	Country	Participants	Assessment tools	Frequency of measurement	Exercise Modality	Description of control	Exercise Intensity	Exercise Dose (minutes)
Fernandez-Abascal et al., 2023	Spain	Enrolled = 48 Analysed = 47 Males = 29 (60.4%) Females = 19 (39.6%) Age ≈ 44.73	Pedometer BREQ-2 IPAQ	Three times (Pre, Post & 24 months follow-up)	Mixed aerobic activities including vigorous walking	TAU; standard clinical management of psychiatric outpatients	Gradual increase in intensity within session to attain 75% of theoretical maximum heart rate	Session: 120 Three times per week for 12 weeks Weekly: 460 Total: 4320
Ryu et al., 2020	Republic of Korea	Enrolled = 60 Analysed = 50 Males = 30 (50%) Females = 30 (50%) Age ≈ 38.35	Pedometer K-PASE	Twice (Pre & Post)	Outdoor cycling	Occupational Therapy group	'Moderate intensity' (for example 16km/h following pacemaker)	Session: 90 Once a week for 16 weeks Weekly: 460 Total: 1440
Shamida et al., 2019*	Japan	Enrolled = *32* Analysed = 31 Randomisation stratified by sex and age but no specific data provided.	SANS QLS (Sense of purpose, motivation & curiosity)	Twice (Pre & Post)	Treadmills and stationary bikes	TAU; regular meeting with psychiatrist, case management & rehabilitation programmes	Session intensity was calibrated to 60-80% of aerobic capacity, with a requirement to engage in 75% of each session	Session: 60 Twice a week for 12 weeks Weekly: 120 Total: 1440

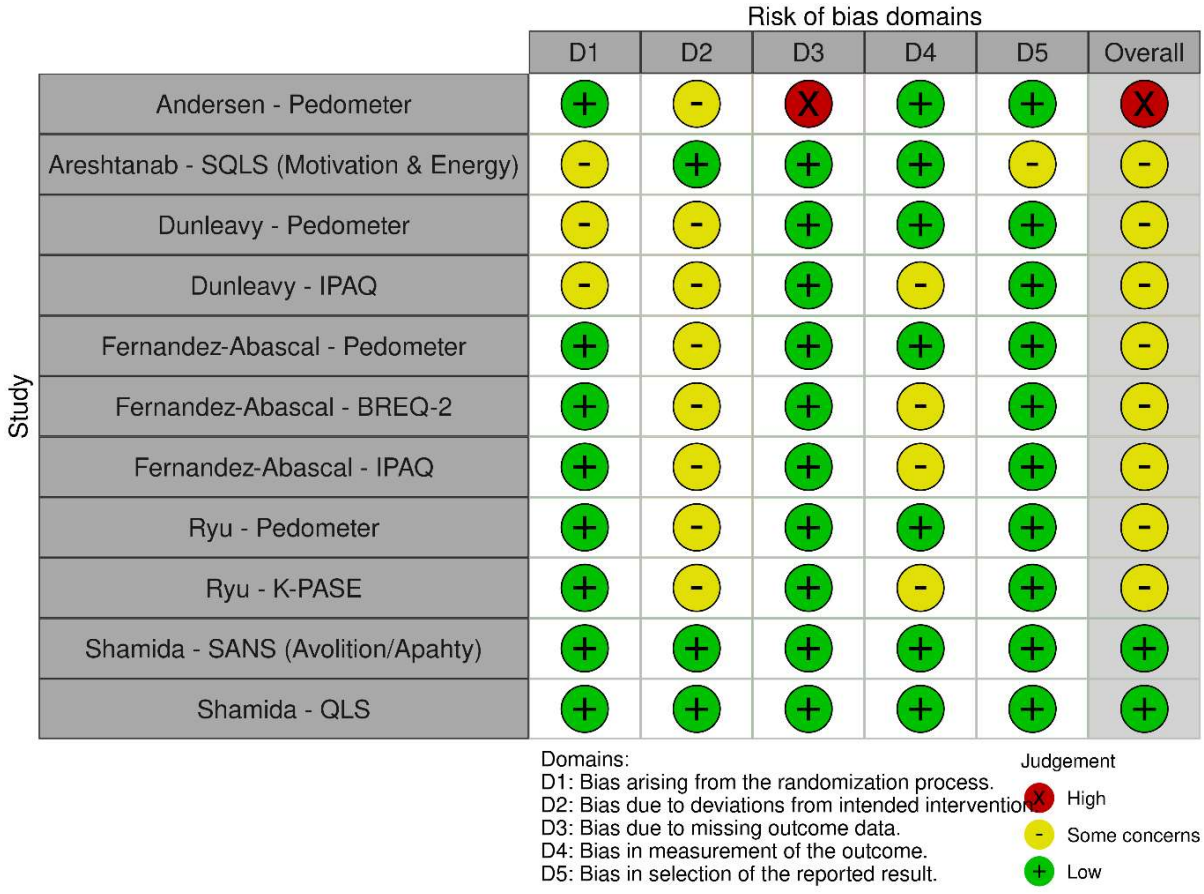
*Pilot or feasibility trail

3.3 Risk of Bias Analysis

One study was categorised as high risk, four studies (including eight outcome measures) were categorised as some concerns (SC), and one low risk. A summary of the results are provided in Figure 3.

Deviation from intended intervention were responsible for the majority of identified bias, mainly due to analysis methods. The presence of self-report measures was relevant for the scoring of item 4.5 'Is it likely that assessment of the outcome was influenced by knowledge of intervention received?'. Previous research suggests that 'some concerns' is a fair judgement as a fair proportion of participants will be unable to discern a health intervention from usual care (Crocker et al., 2023).

Figure 3. *Risk of Bias 2 summary of domains and overall risk categorisation (McGuinness & Higgins, 2020)*



3.4 Preliminary synthesis

Across the six included studies and eleven outcome measures, findings and strength of effect varied considerably (see Table 2). Two of the six studies reported only significant findings in favour of a potential effect of exercise on motivation (Areshtanab et al., 2021; Shimada et al., 2019). One of these studies had the largest sample size (n = 68), and the other was the only study rated as low risk of bias. Both reported large effect sizes across the three measures, though these findings should be interpreted cautiously given the limited number of studies and participants.

Two further studies reported mixed findings (Fernandez-Abascal et al., 2023; Ryu et al., 2020). Pedometer data from both studies appeared to support a possible effect of exercise on motivation. Ryu et al.'s (2020) pedometer data was associated with a medium (nearing large) effect size (d = 0.72). Fernandez-Abascal et al. (2023) did not find a significant effect between steps at post-intervention, but this does not account for the relative increase in steps between the experimental (1,301) and control (249) groups. A group × time interaction analysis suggested a significant effect (p = .009).

Two studies reported non-significant findings (Andersen et al., 2020; Dunleavy et al., 2024). These studies, along with their methodological features, are examined in more detail in the following section.

3.5 Exploring Relationships Within and Between Studies

3.5.1 Methodological Quality and Outcomes

A possible pattern emerged between the methodological quality of studies and the direction of their findings. The two studies reporting exclusively supportive and statistically significant effects of exercise on motivation, Areshtanab et al. (2021) and Shimada et al. (2019), were either associated with larger sample sizes or rated as low risk of bias. While Shimada et al. (2019) had a smaller sample, it was the only study assessed as low risk across all domains using

Table 2 – *Outcome Data and Risk of Bias across Included Physical Activity Studies*

Study	Measure	*N*	*p*	*d*		*Group X Time p*	RoB
Andersen et al., 2020	Pedometer	47	0.9	0.2	Small	n/a	High
Areshtanab et al., 2021	SQLS (motivation & energy)	68	**0.001****	1.12	Large	n/a	Some Concerns
Dunleavy et al., 2024	Pedometer	15	>0.05	Not Reported †		n/a	Some Concerns
	IPAQ		> 0.05	0.07	Small	n/a	Some Concerns
Fernandez-Abascal et al., 2020	Pedometer	48	0.594	0.21	Small	**0.009****	Some Concerns
	IPAQ		0.895	0.04	Small	0.736	Some Concerns
	BREQ-2 (Intrinsic Total)		0.835	0.04	Small	0.055	Some Concerns
	BREQ-2 (Extrinsic Total)		**0.022***	0.71	Medium	0.179	Some Concerns
	BREQ-2 (Demotivation)		0.142	0.07	Small	0.294	Some Concerns
Ryu et al., 2020	Pedometer	50	**0.019***	0.72	Medium	**0.03***	Some Concerns
	K-PASE		0.990	Not Reported		n/a	Some Concerns

Study	Measure	*N*	*p*	*d*		*Group X Time p*	RoB
Shamida et al., 2019	SANS (avolition & apathy)	31	**0.011***	0.97	Large	**< 0.01****	Low
	QLS		**0.029***	0.82	Large	**< 0.05***	Low
Total		259					

Bold reporting indicates significant effect.

†Not reported indicates necessary descriptive data required for effect size analysis are missing.

the RoB2 tool, and it reported large effect sizes on two observer-rated measures. Areshtanab et al. (2021), while being rated as ‘some concerns’ for risk of bias, included the largest analysed sample and reported a large effect on the motivation and energy domain of the SQLS.

In contrast, the two studies reporting no significant findings, Andersen et al. (2020) and Dunleavy et al. (2024), were either underpowered or associated with notable methodological limitations. Dunleavy et al. (2024), for example, was an early-stage pilot randomised controlled trial that recruited only 17 participants, of whom 15 completed the study. A G*Power analysis conducted post hoc indicated that, for a study of this size, the minimum detectable effect size was d = 1.57 (two-tailed independent sample t-test, α = .05, power = .80). This indicates that the study was unlikely to have been adequately powered to detect realistic changes in motivation.

Andersen et al. (2020), while involving a larger sample, was the only study to receive an overall “high risk of bias” rating using the RoB2 tool. This rating was primarily driven by concerns related to missing outcome data in Domain 3, which further limits the confidence that can be placed in its null findings.

These contrasts tentatively suggest that studies with greater methodological rigour and adequate statistical power may be more likely to detect and report potential positive effects of exercise on motivation, although the small number of studies and variability in design mean this conclusion should be interpreted cautiously.

3.5.2 Measurement Type

Measuring motivation is challenging, often measures of motivation may capture different or minimally overlapping underlying constructs (Luther, Firmin, Lysaker, Minor, & Salyers, 2018). Subjective aspects of motivation, including desire, intention, drive, enjoyment, and interest are internal experiences that are best directly accessed through self-report. Objectively observed aspects of motivation, such as goal directed behaviour, initiation and

persistence of action, response to reinforcement or, amount and intensity of action, can be measured through observer rated tools and actigraphy/pedometer data. The nature of these experiences, the ways they are measured, and the direction of findings have prompted closer examination of how they relate to one another.

Self-report accounted for four of eleven measures included in this synthesis. These were all exercise specific, and included two uses of the IPAQ (Craig et al., 2003b), the K-PASE (Chun, 2012) and the BREQ-2 (Markland & Tobin, 2004). Aside from the extrinsic motivation sub-domain of the BREQ-2, all self-report measures of motivation to exercise were not associated with significant change post intervention.

On the other hand, objectively observed motivation tended to be associated with positive findings. The three observer-rated measures of motivation (SQLS, QLS & SANS) were all associated with both significant findings and large effect sizes.

Objectively measured activity, in the form of pedometers, were used in four studies. The findings here were mixed, two sets of step data was largely supportive of the effect of exercise on motivation (Fernandez-Abascal, Suarez-Pinilla, Cobo-Corrales, Crespo-Facorro, & Suarez-Pinilla, 2022; Ryu et al., 2020), while two sets of results were insignificant (Andersen et al., 2020; Dunleavy et al., 2024).

There is a divergent trend between subjective and observer-rated measures of motivation in terms of findings. Objectively measured activity measures were associated with mixed findings.

3.5.3 Psychometric Properties

Across the six measures examined, most demonstrated strong psychometric properties, although reliability and validity varied by instrument and domain. The SANS showed excellent internal consistency ($\alpha = 0.969$) and inter-rater reliability (ICC = 0.985), with strong convergent validity ($r = 0.76$) and good diagnostic accuracy (AUC = 0.86), making it highly robust for assessing negative symptoms (Andreasen, 1989; Kumari, Malik, Florival, Manalai,

& Sonje, 2017). The BREQ-2 demonstrated acceptable to good internal consistency (α ≈ 0.78) and good test–retest reliability (r = 0.84), with confirmatory factor analysis supporting a good model fit, indicating strong construct validity (Markland & Tobin, 2004). The SQLS exhibited acceptable overall reliability (α ≈ 0.84) but variable subscale performance (α = 0.61–0.91); while its internal structure is supported, reviews highlight some structural and responsiveness limitations (Luo, Seng, Xie, Li, & Thumboo, 2008; Wilkinson et al., 2000). The K-PASE demonstrated excellent test–retest reliability (r = 0.94) but only modest convergent validity (r ≈ 0.25), suggesting stability over time but weaker alignment with related constructs (Washburn, Smith, Jette, & Janney, 1993). The IPAQ showed more variable reliability, with some domains achieving moderate stability (e.g., sitting ICC = 0.62) but others lower, and modest concurrent validity (ρ ≈ 0.11–0.28), meaning findings should be interpreted cautiously (Craig et al., 2003a; Lee, Macfarlane, Lam, & Stewart, 2011). Finally, the QLS showed excellent inter-rater reliability (ICC = 0.984–0.994) and generally strong internal consistency (α up to 0.95 in key domains), with robust construct validity supported across multiple cultural contexts (Heinrichs, Hanlon, & Carpenter Jr, 1984). Overall, the SANS, BREQ-2, and QLS demonstrate the strongest psychometric support, while SQLS, K-PASE, and IPAQ are reliable but more limited in certain validity domains.

3.5.4 Generalised Motivation

Motivation is a multifaceted construct that can be conceptualised in various ways. Earlier sections have outlined potential mechanisms of therapeutic change related to both task-specific and generalised forms of motivation. In this section, the evidence relating to the possible effect of exercise on generalised motivation is considered in greater detail. The measures in this review that assess broader motivational functioning, consistent with generalised motivation, are the SQLS, QLS, and the avolition and apathy subscale of the SANS.

These measures were used in two studies: Areshtanab et al. (2021) and Shimada et al. (2019), which together accounted for a combined sample of 99 participants. As shown in

Table 2, both studies reported statistically significant findings in favour of the intervention, with large associated effect sizes.

Shimada et al. (2019) was assessed as having a low risk of bias, whereas Areshtanab et al. (2021) was rated as having “some concerns.” These concerns primarily related to deviations from the intended intervention and potential bias in the selection and reporting of outcomes. Specifically, there were issues regarding the reporting of baseline characteristics, suggesting possible problems with randomisation, as well as the absence of a pre-specified analysis plan.

Taken together, the small number of studies and their methodological limitations warrant cautious interpretation. While the findings provide some indication that exercise interventions could positively influence general motivational functioning in individuals with schizophrenia, stronger conclusions cannot be drawn at this stage.

3.5.5 Task-Specific Motivation

In contrast to general motivational constructs, task-specific motivation refers to motivation directed towards a particular behaviour or outcome (e.g. exercise). Within the included studies, task-specific motivation was assessed using both self-report measures and pedometer data.

The self-report tools aimed to capture an individual's beliefs, intentions, or perceived behavioural regulation related to physical activity. Although pedometer data is collected objectively, it can also be considered relevant in this context, as it reflects behavioural engagement with the target activity and provides a direct indication of whether individuals initiated or sustained exercise behaviour.

As detailed in Table 2, findings from both types of measure were mixed and appeared generally less supportive than those associated with general motivation. For instance, three self-report measures were associated with non-significant results (Dunleavy et al., 2024; Fernandez-Abascal, Suarez-Pinilla, Cobo-Corrales, Crespo-Facorro, & Suarez-Pinilla, 2023;

Ryu et al., 2020). As touched on previously, the pedometer data from Andersen et al. (2020) and Dunleavey et al. (2024) did not provide evidence supporting an effect of exercise on motivation to exercise.

Some support for a possible effect was observed in Fernandez-Abascal et al. (2023), where the BREQ-2's extrinsic motivation subscale showed a statistically significant change. Similarly, Fernandez-Abascal et al. (2023) reported a statistically significant group × time interaction in pedometer-measured step count ($p = .009$), although the pre–post difference in the intervention group was not statistically significant when considered independently. Ryu et al. (2020) also reported a significant and medium effect size associated with an increase in pedometer steps following their cycling intervention.

Taken together, the evidence suggests a mixed picture: while some findings indicate that individuals may increase physical activity following an intervention, these changes are not consistently reflected in self-reported motivation to exercise.

3.5.6 Dose and Intensity

Across the included studies, there was considerable variation in the total duration and weekly dose of physical activity interventions. Total intervention time ranged from 720 minutes to over 4,000 minutes, and the frequency of sessions varied from two to five times per week. There were no consistent relationships between intervention dose and the presence or magnitude of effect on motivation. For example, Fernandez-Abascal et al. (2023) had by far the highest intervention dose but was associated with mix findings on the BREQ-2 and supportive pedometer data. Areshtanab et al. (2021) on the other hand had the lowest dose but was associated with the largest magnitude of change. On the basis of the available evidence, no clear pattern emerged linking motivational outcomes to either intervention volume or frequency.

3.5.7 Exercise Type and Format

All six studies included aerobic exercise as the core intervention component, with some incorporating additional elements such as warm-ups, group-based formats and counselling. The absence of resistance or strength-based training activities within this review mean that there is no suitable comparison for aerobic exercise. While some interventions were delivered in a group context and others individually, this distinction was not systematically examined across studies, and no consistent pattern of effectiveness was associated with format. Given the small number of studies and the relatively homogeneous intervention types, the influence of exercise modality or delivery format on motivational outcomes remains unclear.

3.6 Assessing the Robustness of the Synthesis

Synthesis robustness was measured against study quality, consistence of findings and transparency of the synthesis as outlined previously in narrative synthesis guidance.

3.6.1 Study Quality

Across the six included studies, quality was variable. Only one study (Shimada et al., 2019) was rated as low risk of bias, and this was associated with large, statistically significant effects. Other supportive findings came from studies with “some concerns” (e.g., Areshtanab et al., 2021), while non-significant results were more common in studies with higher risk of bias or smaller samples.

It is important to note that while the RoB2 is a well-regarded and comprehensive tool for assessing risk of bias, its criteria are more readily met by pharmacological trials and may systematically disadvantage psychological research (Munder & Barth, 2018). For instance, the absence of double blinding, common in psychological and behavioural interventions, is often rated as a methodological shortcoming. However, such limitations are frequently unavoidable in this context and may reflect an inherent feature of the research design rather than a flaw in study quality.

Given these considerations, the overall robustness of the synthesis with respect to study quality should be regarded as moderate at best. While the apparent association between study quality and direction of findings provides some indication of consistency in the results, stronger conclusions cannot be drawn. In particular, the limited number of high-quality studies, combined with methodological challenges such as small sample sizes and reliance on self-report measures, constrains the strength of the overall conclusions. While the synthesis highlights possible trends suggesting that exercise may benefit general motivation, these indications should be interpreted cautiously in light of the variable quality of the evidence base and the limitations of the RoB2 framework when applied to psychological research.

3.6.2 Consistency and Coherence of the Evidence

Findings related to general motivation appeared relatively consistent and somewhat supportive, particularly when assessed using observer-rated measures such as the SANS, QLS, and SQLS. Both studies employing these tools reported statistically significant improvements, with large effect sizes, and were among the more methodologically robust trials in terms of risk of bias and sample size.

Interestingly, findings for task-specific motivation were also consistent, although in a different direction. Self-report measures of motivation to exercise, including the IPAQ, K-PASE, and most subscales of the BREQ-2, were uniformly non-significant across studies.

Objective measures (pedometers) showed more variability, with two studies reporting significant increases in step count and two reporting no significant changes. This variation may reflect methodological differences or external factors influencing behaviour that are not captured by motivation alone.

Taken together, the consistency of findings appears to be domain dependent. While the evidence relating to generalised motivation provides some indication of potential benefits, stronger conclusions cannot be drawn given the small number of studies and their

methodological limitations. The evidence for task-specific motivation remains mixed overall, but the uniformity of non-significant self-report findings does suggest a degree of internal consistency. However, this pattern may reflect limitations in measurement sensitivity and validity, rather than providing conclusive evidence about the absence of intervention effects.

3.6.3 Transparency and Rigour of the Synthesis Process

The narrative synthesis approach has been described clearly in previous sections. Studies were grouped according to the type of motivation assessed (general versus task-specific) and by measurement method (observer-rated, self-report, or objective), enabling structured comparison while preserving conceptual distinctions.

Interpretive judgements were guided by both theoretical literature and patterns observed within the data. Reflexive considerations are discussed in the later paragraphs. The use of a second reviewer during the risk of bias appraisal also helped to reduce subjectivity and improve the rigour of study-level quality assessments.

Taken alongside the evidence of study quality and consistency of findings, this synthesis demonstrates several strong features of robustness. While inconsistencies in the direction of findings and methodological limitations in some studies represent constraining factors, the transparency and rigour of the synthesis process enhance its credibility. Furthermore, the convergence of findings in studies with higher methodological quality and larger sample sizes supports a judgement of the synthesis as being of moderate overall robustness.

4.0 Discussion

This narrative synthesis found variable evidence regarding the impact of exercise on motivation in schizophrenia. When considered alongside methodological quality and consistency, the findings tentatively support the hypothesis that exercise can enhance motivation. Evidence was strongest for generalised motivation, particularly in studies using observer-rated measures and larger samples. In contrast, task-specific motivation showed

limited support, with most self-report measures yielding non-significant results, though one study reported a moderate effect in a specific subdomain.

4.1 Generalised Motivation

The strongest evidence from this review supports the positive effect of exercise interventions on generalised motivation. The studies demonstrating this effect included the largest sample sizes, reported large effect sizes, and, in the case of Shimada et al. (2019), were the most methodologically robust in terms of bias control. The findings regarding generalised motivation are derived from only two RCTs and should be interpreted with appropriate caution, even though these studies accounted for roughly one-third of the total review sample. However, on the basis of the available evidence, it is reasonable to reject the null hypothesis for the effect of exercise interventions on generalised motivation.

Notably, all three supportive measures were blinded, observer-rated tools. Comparisons across different types of motivational assessment suggest that observer-rated measures are likely to be the most valid and reliable in this context (Luther et al., 2019). However, it is worth noting that more recent instruments, such as the Clinical Assessment Interview for Negative Symptoms (CAINS), are generally preferred over older tools like the SANS due to improved construct validity and psychometric properties.

Exercise may stimulate a general sense of motivation in two ways. First, people with schizophrenia have pronounced cognitive difficulties associated with their illness and this may impact their ability to plan, organise and evaluate the benefits of specific motivated behaviours (Sharma & Antonova, 2003; Tan, 2009). Exercise improves cognitive functioning in people with schizophrenia and this may therefore facilitate downstream motivated behaviour through increased capacity to engage in goal directed behaviour and daily activities (Firth et al., 2016).

Second, defeatist cognitions are thought to be a key mechanism in the maintenance of negative symptoms of schizophrenia (Saperia et al., 2025). Exercise is likely to represent the

successful achievement of a goal-directed behaviour, thereby providing individuals with concrete, experiential evidence that contradicts defeatist beliefs. This behavioural evidence may help destabilise entrenched self-perceptions of being unmotivated or incapable. In line with dual-process models of self-judgement, such as that proposed by Robinson and Clore (2002), this process may be especially important where semantic self-beliefs dominate due to a lack of vivid episodic memories that challenge them. Through repeated engagement in structured, goal-oriented activity, exercise may gradually shift both behavioural patterns and underlying self-concepts related to motivation.

Interestingly, the patterns found above run counter to a well-established finding in the schizophrenia literature. Typically, subjective reports of hedonic experience remain relatively intact, while observer ratings suggest diminished expressive behaviour (Oorschot et al., 2013). In this review, the reverse appears to be true: motivation-related behaviours (as rated by observers) show improvement, while self-reported motivation remains largely unchanged.

This raises important questions about how motivation is experienced versus expressed in this population. One possible explanation is that these behavioural shifts reflect the reactivation of latent action patterns or structured routines, rather than a conscious internal change in motivational state. Such improvements may therefore represent expressive motivational enhancement, indicating outward indicators of goal-directed drive without necessarily involving a shift in subjective experience.

4.2 Task-Specific Motivation

The available evidence for exercise interventions effect on task-specific motivation is generally non-supportive. The evidence for this research question is more nuanced and would benefit from being explored by measurement type. Self-report measures represented four of the eight measures contributing to the evidence, and aside from one domain of the BREQ-2, were associated with insignificant findings. However, these findings may instead reflect a limitation of using self-report measures in schizophrenia research.

Prior research indicates that individuals with schizophrenia often report physical activity levels that diverge from objective measures (Duncan, Arbour-Nicitopoulos, Subramaniapillai, Remington, & Faulkner, 2019; Duncan, Arbour-Nicitopoulos, Subramanieapillai, Remington, & Faulkner, 2017). Moreover, there is evidence that self-report measures of cognitive performance in people with schizophrenia do not correlate with actual cognitive performance scores (Durand et al., 2015). This is suggestive of impairments in introspection and the expression of internal states that would limit the validity of self-report measures of motivation (Durand et al., 2015; Medalia, Thysen, & Freilich, 2008). It is possible that these difficulties are shaped by general semantic self-beliefs, such as “I have no motivation,” rather than by episodic recall of specific experiences. In the absence of vivid, countervailing memories, these stable self-concepts may influence responses across motivational domains regardless of actual behavioural engagement (Robinson & Clore, 2002).

Evidence from objective measures of physical activity were also mixed, although were evenly split between supportive and non-supportive findings. Supportive findings came from studies with higher sample sizes, but with some moderate risk of bias ratings. Non-supportive studies were associated with moderate to high risk of bias ratings, and one studies with a very small sample. Objective measures of physical activity have been validated for use in negative symptoms, particularly as a behavioural proxy for goal-directed motivation (Meyer et al., 2019; Strauss et al., 2022; Umbricht, Cheng, Lipsmeier, Bamdadian, & Lindemann, 2020). Therefore, it is possible that again these non-supportive findings are associated with methodological rigour rather than effect of exercise. However, it may also be the case that expecting additional physical activity beyond the structured intervention is an unrealistic indicator of increased motivation.

In summary, the evidence associated with exercise interventions and their effect on task-specific motivation to exercise is complicated by a variety of factors, including methodological rigour, measurement validity and risk of bias issues. Although the limitations in studies which did not find an effect are compelling, these do not outweigh the trend in

support of the null hypothesis. However, given the complexity and range of factors considered, this conclusion is made tentatively.

4.3 Limitations

This systematic review had several limitations. The number of studies that met inclusion criteria was limited to six, many of which had small sample sizes. From a power analysis perspective, this is likely to have constrained the range of detectable effects, increasing the risk of type II errors. A total sample of 259 participants is lower than comparable reviews (Sabe et al., 2020), and reflects the advancement of negative symptom research, in the need to understand mechanistic processes in a detailed granular way (McLeod, 2022), which often involves smaller, more targeted studies focusing on specific symptom domains or intervention mechanisms. In the present study, as evidence is further distilled by motivational subtypes and measurement methods, the strength of effect, certainty, and generalisability progressively diminish.

A key limitation of this review relates to the decision to restrict the search to studies published from 2010 onwards. While this cut-off was chosen to limit the confounding effects of older generation anti-psychotics on physical activity (Rismayer, Kambeitz, Javelle, & Lichtenstein, 2024), the decision inevitably limited the breadth of the review and may have excluded high quality studies with important contributions in this area of research.

4.4 Reflexivity

It is important to reflect on the influence of the reviewer's positionality in shaping the interpretation of findings. While efforts were made to follow systematic procedures and incorporate feedback from independent reviewers, the selection of focus areas, interpretation of motivational constructs, and emphasis on clinically observable outcomes have inevitably been influenced by the author’s clinical experience and perspective.

4.5 Future Direction

Future studies would benefit reviews by publishing sub-domains of negative symptom measures. Negative symptoms represent a diverse set of symptoms with different mechanistic targets. The emergence and continued traction associated with transdiagnostic interventions for negative symptoms will elevate the importance of more granular domain specific findings. Moreover, as these measures are regularly used in schizophrenia research, data on motivation would increase without significant additional cost or effort.

4.6 Conclusion

This review provides cautious support for the conclusion that exercise interventions can enhance motivation in individuals with schizophrenia, although the nature and extent of this effect depend on how motivation is defined and measured. Observer-rated measures of generalised motivation consistently demonstrated positive effects, particularly in studies with larger sample sizes and stronger methodological rigour. In contrast, self-reported measures of task-specific motivation yielded weaker or non-significant findings. This discrepancy highlights the limitations of self-report tools in this population and underscores the need for more valid observer-rated or objective measures in future research.

Despite these challenges, the findings suggest that exercise may enhance general motivation, potentially through improvements in cognitive functioning and by providing experiential evidence that counteracts defeatist beliefs. Future research should refine motivational outcome measures, include follow-up assessments, and examine domain-specific effects across different clusters of negative symptoms. Addressing methodological limitations, such as small sample sizes and inconsistencies in measurement, will be essential to strengthening the evidence base and guiding the clinical application of exercise-based interventions in schizophrenia.

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Chapter 2: Empirical Project

Title: Exploring the effect of a novel psychological intervention for negative symptoms based on transdiagnostic mechanisms of change

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Plain Language Summary

Some people with schizophrenia experience “negative symptoms” such as low motivation and difficulty expressing emotions. These symptoms can seriously affect everyday life and are often hard to treat. Most current therapies are long, expensive, and not always effective. Newer approaches focus on specific psychological difficulties that might be causing the symptoms, using a more personalised and flexible format.

This study tested a new type of therapy designed to target the specific psychological processes thought to cause negative symptoms. The therapy was delivered to three in-patients with schizophrenia who had strong negative symptoms. It involved up to 18 sessions and was adapted for each person. The study used several tools to measure the impact of the therapy, including interviews rated by a clinician, activity monitors that tracked physical movement, and questionnaires about motivation and treatment satisfaction.

The results showed that the therapy did not lead to clear or consistent improvements in symptoms or activity levels. Two of the three participants did show small improvements, but these were not strong enough to draw firm conclusions. However, most participants reported feeling more motivated and satisfied with the therapy experience.

These findings suggest that while the new intervention was well received by participants, it did not lead to major changes in behaviour or symptoms. This highlights how difficult negative symptoms can be to treat and suggests that future research should look at how to adapt therapies for people with low motivation and cognitive difficulties, and how to better measure meaningful internal change.

Abstract

Negative symptoms are commonly associated with a diagnosis of schizophrenia. They include expressive and motivational impairments and contribute to significant functional disability. Current psychological interventions often target broad symptom clusters, are lengthy and costly, and show limited efficacy. Mechanistically targeted, modular interventions that are person-centred and collaboratively structured may offer a more efficient, effective and tailored approach.

This study used a single-case experimental design (SCED) with multiple baselines to evaluate a novel intervention targeting specific psychological mechanisms underpinning negative symptoms. Three in-patient participants with schizophrenia and prominent negative symptoms received the intervention which lasted up to 18 sessions. Outcomes were assessed using a clinician-rated interview (CAINS), physical activity monitors (GENEActiv™), and self-report motivation measures (IMI-SR). Treatment satisfaction was assessed post-intervention using the CSQ-18A. Visual analysis was used to examine non-statistical evidence of change across time.

The intervention was not associated with consistent or substantial change in clinician-rated symptoms or physical activity across participants. While two participants showed reduced CAINS scores and higher mean activity levels, these trends were not visually robust. However, self-reported motivation increased in two cases, and satisfaction ratings were consistently high, suggesting the intervention was subjectively beneficial.

These findings suggest that while the intervention was acceptable and potentially engaging, its measurable impact on behavioural outcomes was limited. This underscores the challenge of treating severe negative symptoms, particularly in individuals with cognitive impairment and low motivation, and highlights the need for refined intervention strategies and possibly different outcome measures in future research.

1.0 Introduction

Negative symptoms (NS) of schizophrenia reflect reductions in behavioural and emotional functioning, including features such as anhedonia, social disinterest, and avolition (Buchanan, 2007). Both factor analytic and network analysis studies identify five distinct domains: avolition, asociality, alogia, anhedonia, and diminished expression (Ahmed et al., 2022). These symptoms are pervasive and profoundly impact an individual's ability to function in everyday life (Jobe & Harrow, 2005). The severity of NS predicts poorer occupational, social, and recreational functioning, reduced family integration, and lower quality of life (Foussias, Agid, Fervaha, & Remington, 2014). These impairments also contribute to greater healthcare demands and economic burden (Correll, Xiang, Sarikonda, Bhagvandas, & Gitlin, 2024).

Given these consequences, effective interventions for NS are essential. In contrast to positive symptoms, pharmacological treatments have limited effects on NS (Möller & Czobor, 2015), prompting a focus on psychological approaches (Riehle, Böhl, Pillny, & Lincoln, 2020). While psychological interventions can be beneficial, they are often lengthy, costly, and yield limited effects, with weak supporting evidence (Cella et al., 2023; Priebe et al., 2016).

One limitation is the design of these interventions, which typically target broad symptom clusters, for example, 'CBT for Negative Symptoms' (Staring, ter Huurne, & van der Gaag, 2013). This requires treatment manuals to address a wide range of symptom presentations, resulting in expansive content (Lutgens et al., 2017).Consequently, it becomes difficult to tailor therapy to individual needs without straying from the evidence base (Chorpita, Daleiden, & Weisz, 2005). This is problematic, as individuals with NS represent a heterogeneous group (Schormann, Pillny, Haß, & Lincoln, 2023). The result can be treatments for those with motivation and engagement difficulties that include multiple sessions of irrelevant content.

An alternative design strategy involves transdiagnostic, mechanistically targeted psychological interventions. These approaches focus on underlying psychological mechanisms rather than symptom categories and draw on elements across therapeutic modalities. Chorpita et al. (2005) proposed a matching and distillation model, which identifies core intervention components from evidence-based treatments and aligns them with the individual's presenting difficulties.

A notable application of this approach is the 'Feeling Safe' programme, developed for people experiencing persecutory delusions (Freeman et al., 2021). The programme offered a menu of modules aimed at mechanisms such as poor sleep and distressing voices. Clients collaborated with facilitators to select modules relevant to their difficulties. This personalised approach produced large reductions in delusion conviction (d = −0.86) and very large reductions in delusion severity (d = −1.2) compared to a befriending control.

Currently, no modular, mechanistically targeted interventions have been developed specifically for NS, despite growing evidence supporting relevant mechanisms. For example, avolition has been highlighted as a key target for intervention (Strauss et al., 2020). Avolition is closely linked to mechanisms such as self-defeatist beliefs and distorted effort–cost computations, which also contribute to reduced anticipatory pleasure (Pillny, Schlier, & Lincoln, 2020).

The present study introduces a novel, transdiagnostic intervention framework designed to address core psychological mechanisms underpinning NS. The intervention includes modules on goal setting (to support motivation and reduce avolition), cognitive restructuring (to challenge defeatist beliefs), and behavioural strategies (to enhance reward–effort evaluation). By focusing on theoretically grounded mechanisms, the intervention offers a coherent and individualised treatment approach.

This study aims to evaluate the feasibility, acceptability, and potential effectiveness of this modular intervention using a single-case experimental design. It is hypothesised that

participation in the intervention will be associated with measurable improvements in negative symptoms.

2.0 Methods

2.1 Design

This study employed a single-case experimental design (SCED) with multiple baselines across participants. SCEDs are research designs which include baselines alongside repeat measurements, allowing researchers to establish the presence of an effect without committing to large and costly research trials. Because of this they are well suited to evaluating novel interventions determining individual-level effects and variability in treatment response. The design followed recommendations for intervention effectiveness research in rehabilitation and applied clinical contexts (Krasny-Pacini & Evans, 2018).

To enhance internal validity and reduce the influence of external variables, participants were randomly assigned to one of three baseline durations: two, four, or six weeks. This staggered baseline approach supports causal inference by allowing for the observation of changes in outcomes are temporally linked to the introduction of the intervention. Two participants (P1 & P2) baselines were, in effect, extended due to illness of the therapist at the commencement of the intervention. Instead of six and four weeks, their baselines were eight and six weeks respectively. The final participant (P4) was also randomised to a six-week baseline period.

The intervention period lasted up to 18 weeks, including the assessment and formulation session. Participants received one therapy session per week. Outcome measures were administered every two weeks during the baseline phase and every four weeks during the intervention phase.

The study was conducted in routine NHS inpatient psychiatric rehabilitation settings and participants continued to receive standard multidisciplinary input during their involvement. As

such, the use of a multiple baseline design was intended to control for the influence of external therapeutic factors without requiring the withdrawal of standard care.

2.2 Participants

Four participants (three men, one woman) with a diagnosis of schizophrenia were recruited from psychiatric rehabilitation in-patient wards within NHS Greater Glasgow and Clyde. All Participants were aged 18 years or older and identified by local clinical psychologists as potentially suitable based on the presence of persistent primary negative symptoms, adequate cognitive functioning, and the absence of significant positive symptoms or secondary contributing factors. One participant was withdrawn from the study after a severe deterioration in their mental state.

2.2.3 Inclusion & Exclusion Criteria

Participants were eligible if they:

- Scored ≥ 25 on the Clinical Assessment Interview for Negative Symptoms (CAINS), indicating moderate to severe symptomatology,
- Had experienced negative symptoms for at least six months,
- Scored ≥ 25 on the Montreal Cognitive Assessment (MoCA), indicating sufficiently intact cognitive functioning,
- Had sufficient command of English to participate meaningfully in psychological therapy.

Exclusion criteria included:

- Evidence that negative symptoms were secondary to other factors such as prominent positive symptoms, affective disturbance, or substance dependence,
- Diagnosed learning disability or severe cognitive impairment,
- Current engagement in other individual psychological therapies.

2.2.4 Recruitment & Consent Procedure

Initial identification was carried out by ward-based multidisciplinary teams (MDTs), and potentially eligible participants were approached by a known member of their care team to discuss the study and provide the information sheet. If interested, the individual was introduced to the researcher (ZB), who conducted a formal screening assessment including the CAINS and MoCA. Participants who met the inclusion criteria and provided written informed consent were enrolled into the study.

Favourable ethical opinion for the study was obtained from the SW Research Ethics Committee (REC Reference: 24/SW/0084) on 07.08.2025. All participants provided written informed consent, and procedures complied with General Data Protection Regulation (GDPR) and University of Glasgow research governance policies.

2.3 Intervention

The intervention was a modular, mechanistically targeted psychological therapy designed to address specific maintaining mechanisms of negative symptoms in schizophrenia. The approach to intervention design was informed by the distillation and matching model (Chorpita et al., 2005), which identifies common elements across evidence-based treatments to allow for flexible, modular intervention delivery, and by the Feeling Safe programme for persecutory fears (Freeman et al., 2021), which demonstrates how targeted cognitive strategies can be effectively applied within a structured yet personalised framework.

The present intervention also drew on transdiagnostic principles of intervention design, as exemplified by both Chorpita et al.'s (2005) and Freeman et al.'s (2021) work, which emphasise addressing shared psychological mechanisms such as threat overestimation, cognitive avoidance, and safety-seeking behaviours, rather than focusing narrowly on diagnostic categories. This transdiagnostic approach allows interventions to be more adaptable and applicable across a range of clinical presentations, enhancing both relevance

and impact. It was delivered using a flexible, patient-centred structure to enhance relevance and personal engagement.

2.3.1 Intervention Framework

The intervention was organised around a catalogue of modules each addressing theoretically and empirically supported mechanisms underlying negative symptom domains. These modules were drawn from established psychological interventions including cognitive behavioural therapy, cognitive remediation therapy, and social skills training. Modules included:

- Engagement and Goal Setting
- Effort Expenditure and Goal Pursuit
- Addressing Cognitive Difficulties
- Social and Interpersonal Skills
- Addressing Meta-Cognitive Difficulties
- Behavioural coping skills and self-regulation

Each module targeted one or more key dimensions of negative symptoms such as amotivation, anhedonia, avolition, or asociality.

2.3.2 Configuration and Delivery

The treatment targets and associated treatment modules to be tried was determined collaboratively during a structured assessment and formulation session held at the end of the baseline period. Participants were presented with a series of cards describing therapeutic targets (e.g. “enjoying myself more,” “making friends”, “becoming more active”, “increasing my independence”), and were supported to select modules relevant to their experiences. The selected modules were then delivered in a sequence that reflected the individual’s formulation.

The intervention period lasted up to 18 weeks, including the assessment session. Therapy was delivered in weekly one-to-one sessions by a qualified psychologist (HM). Each module was designed to span approximately three to four sessions, although flexibility was maintained to accommodate participant needs. One participant (P4) was recruited with the plan to offer a condensed version of the intervention schedule due to study time constraints. Unfortunately, due to two periods of significant illness requiring medical ward admission P4 received a smaller dose of the intervention than had been originally planned (7 sessions).

2.4 Measures

The primary outcome domain in this study was negative symptoms. Three sources of data were used to assess this construct: a clinician-administered interview, a self-report measure of intrinsic motivation, and objective activity monitoring. This multi-method approach was designed to capture both subjective and behavioural dimensions of negative symptomatology, particularly amotivation, anhedonia, and reduced behavioural initiation.

2.4.1 Clinician-Rated Negative Symptoms

Negative symptoms were assessed using the Clinical Assessment Interview for Negative Symptoms (CAINS), a structured interview that evaluates motivation and pleasure, as well as expressive deficits (Kring, Gur, Blanchard, Horan, & Reise, 2013). It is widely recognised as a gold standard tool in the assessment of negative symptoms and was administered at consistent time points throughout both the baseline and intervention phases.

2.4.2 Physical activity

Objective physical activity indicators of negative symptoms were assessed using GENEActiv™ wearable actigraphy monitors, used continuously throughout both the baseline and intervention periods. These wrist-worn devices recorded continuous physical activity data as a behavioural proxy for engagement in daily life, particularly goal-directed activity associated with avolition and amotivation.

These monitors have been utilised in similar studies as they provide uninterrupted objective metrics on physical activity that are closely associated with validated clinical measures of negative symptoms. This supports their suitability for use in populations with psychosis and limited functional engagement (Meyer et al., 2019; Strauss et al., 2022; Umbricht et al., 2020).

The devices were configured to sample at 20 Hz with a 60-second epoch length. A 20 Hz sampling rate provides sufficient resolution to detect movement in largely sedentary populations while reducing data noise and conserving device battery life (Umbricht et al., 2019). The use of a 60-second epoch allows for meaningful aggregation of movement data over time and is considered appropriate for estimating habitual activity patterns in clinical samples with low mobility levels (Dillon et al., 2016).

2.4.3 Motivation

Intrinsic motivation was measured using the Intrinsic Motivation Inventory for Schizophrenia Research (IMI-SR), a self-report questionnaire adapted for individuals with psychosis (Choi, Mogami, & Medalia, 2010). The IMI-SR prompts participants to rate their engagement and interest in relation to a specific activity. The IMI-SR cannot determine efficacy in the context of the present design, as the measure must be adapted to suit a specific activity (e.g. Recent therapy session), and in the baseline there is, by definition, no activity.

This measure was selected due to its theoretical alignment with Self-Determination Theory (Deci & Ryan, 2012), which offers a theoretical explanation for motivational deficits, as well as its demonstrated sensitivity to changes in motivation. While the measure may not be used to determine efficacy, it will provide helpful contextual information on the role of intrinsic motivation and capacity for insight in this population.

2.4.4 Feasibility, Satisfaction and Acceptability

Feasibility was assessed by examining recruitment, retention rates and session attendance. Qualitative feedback was also gathered to explore participants' experiences and identify potential barriers to implementation.

To assess participant satisfaction with the intervention, the Client Satisfaction Questionnaire (CSQ-18) was administered at the conclusion of treatment (Attkisson & Zwick, 1982). This 18-item self-report instrument is frequently used to evaluate perceived acceptability and service satisfaction in psychological intervention trials. Its inclusion was intended to support an early-stage assessment of the intervention's feasibility and user experience.

2.5 Procedure

Following informed consent, Participants were randomly assigned to one of three baseline durations (two, four, or six weeks), using a restricted randomisation schedule. Randomisation was conducted via a secure online randomisation website.

During the baseline phase, participants wore GENEActiv™ actigraphy monitors continuously and completed outcome measures every two weeks. After completing their assigned baseline period, each participant attended an assessment session. This session included a structured, collaborative exercise in which participants selected treatment modules relevant to their goals and symptom profile.

Intervention delivery began the week following the assessment session. Participants received up to 18 weeks of therapy, including the assessment session, with one session scheduled per week. Outcome measures were collected at four-week intervals throughout the intervention. These included the CAINS, the IMI-SR, and downloads of actigraphy data. This schedule was designed to capture both subjective and behavioural indicators of change in negative symptoms, which aligns with the intervention's theoretical focus on mechanistic processes.

One participant (P4) received a condensed intervention schedule due to recruitment delays. Due to several periods of illness, the participant received a significantly lower dose of the intervention at the completion of data collection.

Accelerometer data were downloaded at two-week intervals during the baseline period and one-month periods during the intervention. Accelerometer data was translated into Euclidian Norm Minus One (ENMO), which is a common metric to use in physical activity data (Migueles et al., 2017). Non-wear time was estimated using established criteria, defined as periods of at least 60 consecutive minutes of near zero ENMO values (≤ 0.03g), allowing for up to 2 minutes of non-zero interruptions (Migueles et al., 2017). Data identified as non-wear were excluded from daily summaries and visual analyses. Missing data resulting from non-wear periods or device malfunction were not imputed. Instead, these instances were transparently represented as gaps in visual plots, consistent with recommendations for visual analysis in single-case designs (Gast & Spriggs, 2014; Lane & Gast, 2014), ensuring that phase comparisons were based solely on observed data.

Data were processed and analysed using R (v4.5.1), a statistical computing environment well-suited to single-case designs and time-series data (RStudio Team, 2023). Raw data were prepared using packages including tidyverse for data manipulation and lubridate for time parsing (Grolemund & Wickham, 2011; Wickham et al., 2019). Visual analyses were conducted using the ggplot2 package in R, a widely used and well-established data visualisation tool within the scientific and statistical communities (Wickham, 2011). Plotting decisions were guided by SCED conventions (Krasny-Pacini & Evans, 2018; Lane & Gast, 2014). All scripts were developed and saved to enable reproducibility (see Appendix J, p86), and plots were exported as high-resolution images for reporting purposes.

2.6 Analysis Plan

This study employed a visual analysis approach to evaluate the effectiveness of the intervention, consistent with recommendations for single-case experimental designs in

applied clinical and rehabilitation research (Krasny-Pacini & Evans, 2018). Given the small sample size and the methodological emphasis on individual-level change, no inferential statistical tests were conducted. SCED and visual analysis guidance are referenced throughout (Gast & Spriggs, 2014; Krasny-Pacini & Evans, 2018; Kratochwill et al., 2010; Lane & Gast, 2014).

Visual analysis focused on five key dimensions across each participant's data series: *level, trend, stability, immediacy of effect, and overlap*. *Level* refers to the mean performance within each phase, allowing comparisons between baseline and intervention periods. *Trend* examines the direction and rate of change over time, both within and across phases. *Stability* reflects the variability of data points within each phase, with more stable data indicating greater reliability of observed effects. Variability was assessed descriptively using standard deviation and interpreted in relation to phase means and visual inspection. No fixed numeric thresholds were applied, given the limitations of applying distributional assumptions to single-case data.

Immediacy of effect considers how abruptly outcome measures change following the introduction of the intervention, in the present case the direction of the first three data points after baseline. CAINS and activity data are plotted at different time points (daily compared to monthly). This means that immediacy effects on these two visual plots will be different by a scale of 30~. Although it would have been possible to present activity data as a monthly mean, thereby matching the scale of data, this would have been at the cost of other visual analysis features (e.g. Variability) and to the overall depth of the visual plot.

Overlap describes the proportion of intervention phase data that falls within the range of the baseline phase, which is a useful indicator of intervention impact. This is measured using percentage of non-overlapping data (PND). PND is used as a non-parametric effect size, with < 50% ineffective, 50-70% questionable effectiveness, 70-90% Effective and > 90% Very effective (Scruggs & Mastropieri, 1998).

For each outcome (CAINS, IMI-SR, and actigraphy), individual time series graphs were produced for each participant. Consistency of effect across participants was then evaluated, with attention paid to whether patterns of change aligned with the introduction of the intervention across staggered baselines.

Data were graphed using standard conventions for SCEDs, with a vertical line indicating phase transition. Trend lines were maintained across missing data, contrary to recommended guidelines (Lane & Gast, 2014).

This decision was based on two considerations. First, omitting the trend line would have made some plots visually cluttered, given the presence of multiple gaps in data. Second, the intervention was designed to support gradual, iterative improvement over time. Given this therapeutic rationale, maintaining continuous trend lines was considered a reasonable and theoretically justified choice.

3.0 Results

3.1 Demographic Summary

All participants in the present cohort had their first psychiatric admission approximately six years ago. Self-harm was a relevant factor in all initial inpatient referrals, with two participants experiencing incidents of such severity that they required acute medical intervention and subsequent hospitalisation. Overall, the cohort has spent substantial periods of time in hospital, ranging from four to six years since their first admission. The number of hospital admissions varied between two and six across participants, reflecting differing levels of clinical need and relapse patterns.

3.2 Outcomes

Figure 4 graphically displays Clinician-Rated Negative Symptoms (CAINS), physical activity, represented as ENMO, and self-report intrinsic motivation scores (IMI-SR) for the three participants. The physical activity and negative symptoms scores span across

s both baseline and intervention phases, while the IMI-SR is only used in the intervention stage.

Table 4 describes the mean and standard deviation for each of the measures split into the two phases where appropriate. PND, and actigraphy non-wear time is also presented alongside these figures.

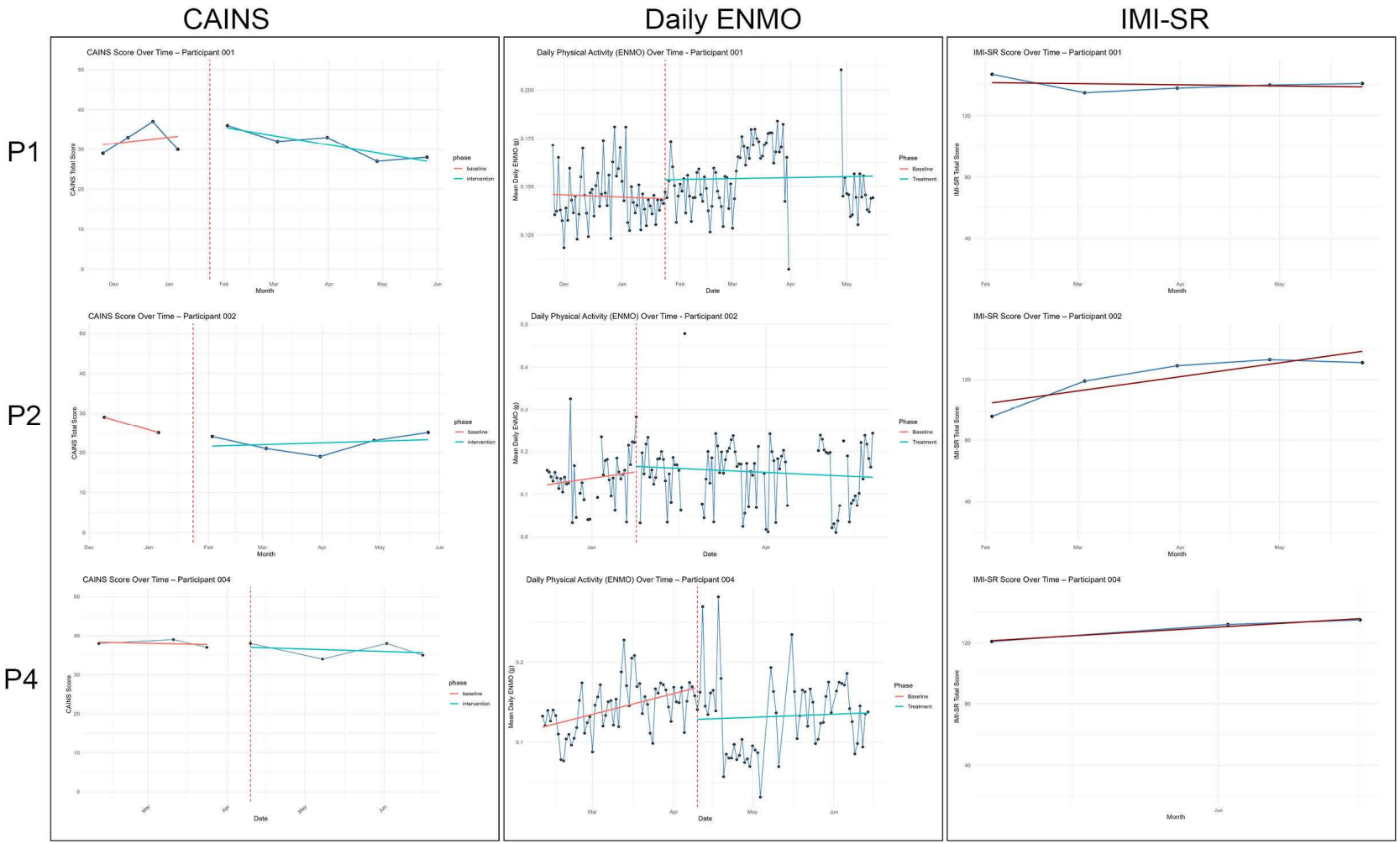
3.2.1 Assessor Rated Negative Symptoms (CAINS)

Across participants, CAINS scores during the baseline period showed limited variability and differing trends. For participant 1, scores exhibited a slight upward trend during baseline (M = 32.25, SD = 3.59). Following intervention onset, the first three data points showed a clear downward shift. The overall trend during the intervention phase was decreasing (M = 31.2, SD = 3.71), although three of the five data points overlapped with baseline scores (PND = 20%).

Table 3. *Demographic Summary and Clinical Context*

	Gender	Age Range	Yr of 1st Admission	Time spent in hospital (Yrs)	# of hospital admissions	Baseline CAINS
A	Female	30-39 yrs	2020	4	6	38
B	Male	30-39 yrs	2019	6	2	29
C	Male	50-59 yrs	2020	4	3	29

Figure 4. *Graphic representation of outcome measure scores over time.*



Supplementary data in the form of large high resolution individual graphs are available in Appendices L, M & N (p88-96)

Table 4. *Descriptive Statistics for Key Outcomes by Phase*

	CAINS			Daily ENMO (g)				IMI-SR
Participant	**Baseline**	**Intervention**	**PND**	**Baseline**	**Intervention**	**PND**	**PNW**	**Intervention**
1	32.25 (3.59)	31.2 (3.71)	20	0.145 (0.014)	0.147 (0.015)	2.4	8.8	140 (4.38)
2	29 (2.83)	22.4 (2.30)	80	0.137 (0.056)	0.153 (0.076)	8.5	62.9	121.6 (14.35)
4	38 (1)	36.25 (1.71)	50	0.138 (0.034)	0.133 (0.048)	5.2	27.3	129.3 (7.57)

Descriptive Statistics for CAINS Scores, Daily Physical Activity (ENMO) in the form of gravitation acceleration (g), Intrinsic Motivation (IMI-SR), and Percent Non-Wear (PNW) for Baseline and Intervention Phases. Data presented as means with standard deviation in brackets.

Participant 2 had only two baseline measurements, with a decrease observed from the first to the second (M = 29, SD = 2.83). After the intervention began, the initial three data points showed a clear downward signal. Despite this, the overall trend was flat with a slight upward tendency (M = 22.4, SD = 2.30). Only one intervention data point overlapped with the baseline range, while the remaining four were lower (PND = 80%).

For participant 4, baseline CAINS scores remained stable with a very gradual decline (M = 38, SD = 1) and minimal variability. After the intervention began, the initial three data points did not show a consistent signal. Despite this, the overall trend was slightly downward with limited variability (M = 36.25, SD = 1.71). Half of the four intervention data points overlapped with the baseline measurements (PND = 50%).

3.2.2 Objective Physical Activity (Daily ENMO)

Across participants, ENMO values during the baseline periods demonstrated mixed variability and limited change over time. For Participant 1, daily ENMO during the 8-week baseline ranged from 0.12 to 0.18 mg (M = 0.145, SD = 0.014) with a very slight downward trend. Following intervention onset, there was an immediate increase in physical activity during the first three data points, with values ranging from 0.07 to 0.21 mg (M = 0.147, SD = 0.015). Despite this early increase, the overall trend during the intervention was flat with slight upward movement, and most intervention data points overlapped with those from baseline. Notably, ENMO values during March clustered above baseline levels, while data from late January, February, and May showed considerable overlap with baseline (PND = 2.4%).

For Participant 2, baseline ENMO values over five weeks ranged from 0.03 to 0.32 mg (M = 0.137, SD = 0.0595) and showed an increasing trend and high variability. The intervention phase produced no clear initial change, with early ENMO values ranging from 0.01 to 0.40 mg (M = 0.153, SD = 0.076). Data during this phase remained variable, with a slight downward trend overall and substantial overlap with baseline measurements (PND = 8.5%).

Participant 4 displayed baseline ENMO values between 0.08 and 0.22 mg (M = 0.143, SD = 0.031) across six weeks, with a clear increasing trend. Following the introduction of the intervention, no distinct shift was observed in the initial data points. Intervention phase values ranged from 0.03 to 0.28 mg (M = 0.133, SD = 0.048), showing increased variability and a slight upward trend overall. The trend was less significantly increasing, and the level was lower than in the baseline period. High overlap between phases was evident, although a distinct cluster of values between mid-April and early May consistently fell below the baseline range (PND = 5.2%).

3.2.3 Intrinsic Motivation (IMI-SR)

IMI-SR scores were collected only during the intervention phase, as the measure captures participants' subjective experience of recent therapy sessions. For participant 1, scores displayed a flat trend with a slight decrease over time and low variability (M = 140, SD = 4.38). Participant 2 showed a strong positive trend in IMI-SR scores across the intervention period with higher variability (M = 121.6, SD = 14.35). For Participant 4, there was a gradual increase in IMI-SR scores and low variability (M = 129.3, SD = 7.57).

3.2.4 Satisfaction with Treatment (CSQ-18A)

CSQ-18As were completed by participants anonymously. The overall satisfaction score indicated that the service received was rated as ‘highly satisfactorily’. Participants were offered an opportunity to reflect on their treatment and offer productive feedback. The feedback provided was very positive and appreciative for the input the participants had received.

3.3 Feasibility

Recruitment began in August 2024. The recruitment spanned four hospitals in the greater Glasgow area. Three initial participants were recruited between November and December 2024, before one individual dropped out due to a deterioration in mental state. Recruitment reopened, and the final participant was enrolled by February 2025. However, the timing of

this recruitment required the intervention to be delivered using a condensed structure. The total recruitment period spanned six months. A total of 7 people were deemed appropriate for approach and of those people 4 agreed to complete an inclusion assessment.

Engagement in the intervention sessions was above 90% in two participants. Due to a period of illness, as well as other engagement issues, another participant attended 8 sessions in the 14 weeks they had to engage in the intervention procedure.

3.4 Patterns of Change

The CAINS clinical threshold is defined as a score of ≥25. Individuals with schizophrenia who do not present with prominent negative symptoms typically score around 19, whereas those with 'persistent' negative symptom profiles score an average of 29 (Li et al., 2018). In the present study, two of the three participants concluded the intervention with scores below the 29-point benchmark, while none completed the intervention with a score below the clinical threshold of 25. One participant remained below the threshold for much of the intervention period prior to the final measurement.

Across participants, CAINS scores showed variable patterns. Two participants exhibited reductions in scores from baseline to intervention conclusion, while the third retained their lowest baseline score at the final assessment. Two participants demonstrated early shifts in their data, with decreases observed within the first three intervention data points, suggesting possible immediacy effects. Two participants also showed downward trends during the intervention phase, whereas one participant's scores followed a marginally increasing trajectory. Overlap between baseline and intervention scores varied: Participant 2's scores fell outside the baseline range on 80% of occasions, Participant 1's scores showed substantial overlap, and Participant 4 displayed overlap of approximately 50%. While these patterns suggest potential signals of change for some individuals, overall, the data do not show consistent patterns across participants.

Normative physical activity data classify a sedentary profile as having an average ENMO of <0.2g (Hildebrand, VT, Hansen, & Ekelund, 2014). All participants had mean ENMO values well below this threshold during both the baseline and intervention phases. Two participants had slightly higher mean ENMO scores in the intervention phase compared to baseline, while the third remained relatively stable. Percent overlap between phases was generally high, and two participants showed stable or marginally increasing trends in activity levels. One participant displayed a possible immediacy effect, whereas there was no clear signal in the other two cases. Given the high degree of overlap (≤10% non-overlapping), there was limited indication of systematic shifts in physical activity between phases.

Intrinsic motivation scores (IMI-SR) also varied across participants. Two participants showed notable increases in their scores during the intervention phase, while Participant 1 maintained consistently high scores throughout, beginning only three points below the maximum possible score at the first measurement. These individual-level trajectories highlight potential signals of change in self-reported motivation for some participants, though patterns were not uniform across the group.

4.0 Discussion

This study aimed to explore the impact of a mechanistically targeted intervention for negative symptoms in people with schizophrenia. The high standard of change required was such that it would be easily identifiable through visual analysis (Gast & Spriggs, 2014; Kratochwill et al., 2010). While this standard was not met, leading us to accept the null hypothesis, the study yielded important insights into the complexity of treating persistent negative symptoms, the challenges of engagement in this population, and the potential value of participant-reported experiences in evaluating intervention impact.

The approach to intervention development used here was influenced by the Feeling Safe programme's success, which focuses on specific symptoms (paranoia) and targets key causal and maintenance factors (Freeman et al., 2021). The key difference between the

difficulties being targeted lies in the underlying mechanistic processes. Persecutory beliefs, as targeted by interventions such as the Feeling Safe Programme, involve a high-energy, aversive disengagement from the external world, driven by threat perception (Freeman, 2007). In contrast, negative symptoms are often characterised by a low-energy form of disengagement, typically involving apathy, reduced drive, and cognitive or motivational deficits, rather than distress or fear.

It is possible that a key treatment-relevant difference between negative and positive symptoms is arousal. The circumplex model of affect defines emotional experience along two axes: valence (positive or negative) and arousal (high or low) (Russell, 1980). Fear and threat are typically associated with high-arousal states, whereas apathy and amotivation (core features of negative symptoms) are characteristic of low-arousal states.

In high-arousal conditions such as paranoia, where fear is prominent, there may be an underlying drive to reduce threat or seek safety. If this motivational drive can be redirected towards therapeutic engagement (for example, through safety-focused interventions like the Feeling Safe programme), it may circumvent problems of engagement and motivation which are typical issues in adult psychotherapy (Swift & Greenberg, 2012), and a particularly problematic part of NS (Gouse & Kline, 2023).This process may help explain why meta-analytic research finds that psychotherapies for anxiety disorders produce higher effect sizes than those for major depressive disorder (Cuijpers, Cristea, Karyotaki, Reijnders, & Huibers, 2016).

In part, the problem may be associated with dopaminergic dysregulation, which in NS impacts reward processing (Juckel et al., 2006). Anhedonia may limit the potential for positive reinforcement, making it less likely that individuals engage in ways needed to derive therapeutic benefit (Cella et al., 2023; Liang, Wu, Hanxiaoran, Greenshaw, & Li, 2022). In contrast, individuals who experience a reduction in fear or paranoia during therapy may be more likely to remain engaged, as the improvement itself serves as reinforcement.

Cognitive impairment is more pronounced in individuals with predominantly NS than in those with primarily positive symptoms (PS), likely reducing their ability to engage with and benefit from psychological interventions (Lysaker & Dimaggio, 2014). Meta-analyses show that people with deficit schizophrenia, a proxy for persistent NS, perform significantly worse across cognitive domains, particularly processing speed, attention, memory, and social cognition (Bora, Akdede, & Alptekin, 2017).These differences (Cohen's $d \approx 0.3–0.8$) are evident even in drug-naïve, first-episode cases and are most severe among those with high negative symptom burden (Zhang et al., 2024).

A MoCA score of ≥ 25 was set for eligibility, based on previous research into cognitive impairment in long-term psychosis patients (Gil-Berrozpe et al., 2020). However, cognitive impairment as assessed by general screening tools and the capacity to benefit from an intervention grounded in cognitive behavioural theory may not be equivalent. It is possible that some participants, although meeting the screening threshold, still lacked the cognitive resources needed to fully engage.

Another key distinction between NS and PS lies in the extent to which they are intrapsychic in nature. PS are typically understood as direct manifestations of illness, such as hallucinations or delusions. In contrast, NS are not simply the result of internal processes; they involve complex systemic factors (Fusar-Poli et al., 2013).For example, a person with NS is not socially amotivated in a vacuum. This amotivation occurs within the broader context of a stigmatised mental illness, often reinforced by negative societal and familial attitudes (Thornicroft, Brohan, Rose, Sartorius, & Leese, 2009). In such environments, demotivating beliefs may reflect a harsh reality, particularly within inpatient settings, and may therefore not respond to interventions that target intrapsychic processes alone.

In summary, differences in arousal, motivation, reinforcement and context suggest that interventions effective for positive symptoms may not readily translate to negative symptoms and instead require iterative interpretation and adaptation.

Despite the potential challenges that could affect engagement, participant feedback and self-report measures in the present study were generally positive and supportive of the intervention. End-of-study feedback indicated appreciation for the intervention and a perceived benefit from participation. This was reflected in high CSQ-18A scores, which exceeded the satisfaction threshold, and similarly elevated scores on the IMI-SR. Overall, self-report data indicated that the intervention was perceived as successful by participants.

It is therefore noteworthy that this positive feedback was not consistently reflected in the two main outcome measures. Although CAINS scores generally decreased, all participants remained at or above the clinical threshold of 25 post-intervention. Similarly, average ENMO values remained below 0.2g, a level typically classified as sedentary (Buchan & Baker, 2023). It is possible that participants' positive feedback reflects a meaningful therapeutic experience, even if not captured through measurable behavioural change. Tools such as actigraphy monitors and the CAINS rely primarily on observable indicators and may not fully capture internal shifts that participants perceived as beneficial.

In addition to high acceptability, several indicators suggest initial feasibility of the intervention. Participants engaged with the full course of therapy, the CAINS and IMI-SR outcome measures were successfully collected with minimal missing data, and the intervention was deliverable within routine inpatient settings without requiring substantial resource adaptation. However, reaching the intended recruitment threshold proved challenging, reflecting known difficulties in engaging this population. Moreover, there were high rates of non-wear time with actigraphy monitors which would have implications for missing data in larger scale studies.

4.1 Limitations

One consideration in understanding the observed results relates to the suitability of SCED methods for detecting small treatment effects. While this design is useful for assessing individual-level change, it is not well suited to detecting smaller effects. It is possible that the

intervention had a meaningful impact that could have been identified with a larger sample and the application of inferential statistics.

In this study, inclusion criteria required negative symptoms to be primary in presentation. However, this initial assessment was carried out by clinicians within the rehabilitation settings and was not formally verified using a structured diagnostic tool or standardised criteria. As a result, it is possible that some participants may have presented with secondary negative symptoms arising from factors such as prominent positive symptoms, medication side effects, or comorbid conditions. This limitation should be considered when interpreting the findings, as the presence of secondary negative symptoms may have influenced participants' responsiveness to the intervention and the generalisability of the results.

Another limitation concerns engagement and adherence to the measurement protocol. Two of the three participants experienced difficulties that may have affected the results. One participant had two significant periods of illness that reduced their capacity to attend therapy sessions. Another had a non-wear time of 63 percent, considerably higher than the expected range of 33 to 37 percent associated with routine removal for sleep and personal care. While equipment malfunctions were confirmed on several occasions, it is also possible that other non-random factors contributed to the extended non-wear time. For example, the device may have been deliberately removed during periods of physical activity or rest, potentially skewing the data in ways that are difficult to account for.

Another limitation involves the use of the IMI-SR. The measure could not be administered during the baseline phase, which meant that although several positive trends were observed, there was no baseline data against which to assess progress. In addition, there are questions regarding its validity. The IMI-SR has a maximum score of 147. As illustrated in the graphs, one participant consistently scored at or just below this maximum, while another remained comfortably above the 130 threshold. These high scores suggest a possible ceiling effect, raising concerns about the measure's sensitivity to change over time.

Another area of consideration in terms of limitations involves the role of the author in data collection. There were potential biases that could have skewed the results. For example, the CAINS is an assessor-rated measure of negative symptoms. Although structured, it was completed by the author, who had a vested interest in the intervention's success. This is clearly a position that's vulnerable to unconscious influence. Another issue relates to the completion of the IMI-SR. While participants were told their responses wouldn't be shared with the intervention facilitator, the consistently high scores raise the possibility that some responses were shaped by social desirability.

It was not possible to reflect on the practical aspects of delivering the intervention within this study, as the author was not involved in its implementation. Consequently, no direct insights were gained regarding potential challenges or facilitators related to session delivery, participant engagement, or intervention fidelity. Future research may benefit from incorporating feedback from facilitators to better understand these factors and inform refinements to the intervention protocol.

4.2 Future Direction

Future research could explore psychosocial treatment protocols, such as behaviourally activating interventions that place fewer cognitive demands on participants and reduce reliance on cognitive restructuring. Researchers should also consider using measures of negative symptoms that are less dependent on behavioural indicators of change. Furthermore, employing a similar design with a longer recruitment period may help achieve a larger sample size that is less affected by individual illness or unforeseen events.

Methodologically, employing a similar design with an extended recruitment period may support larger sample sizes and improve generalisability. Longer timelines could also help mitigate the impact of individual illness trajectories, fluctuations in mental state, and unforeseen external events on data completeness. Future studies might also explore hybrid

designs that combine mechanistic single-case methodologies with larger cohort analyses, balancing in-depth individual data with broader applicability.

In addition, researchers might consider using measures of negative symptoms that are less dependent on observable behavioural change. Current assessment tools may underestimate subtle shifts in internal experiences such as anticipatory pleasure or motivation, meaning interventions could have beneficial effects that remain undetected by standard behavioural indicators. Using multi-method assessment strategies, combining clinician-rated measures with self-report and ecological momentary assessment, could offer a more nuanced understanding of change over time.

4.3 Conclusion

This study evaluated a modular, mechanistically targeted psychological intervention for negative symptoms in schizophrenia using a single-case experimental design. While the intervention was associated with some encouraging trends in clinician-rated symptoms and physical activity for select participants, consistent and robust improvements were not observed across all outcomes. Nevertheless, high levels of participant satisfaction and self-reported motivation suggest the intervention was acceptable and subjectively beneficial. These findings highlight the complexity of treating negative symptoms, particularly when accompanied by cognitive deficits, and more broadly, the challenge of engaging individuals in therapy who experience persistent motivational and engagement difficulties. Future research should refine intervention strategies to enhance engagement, reduce cognitive load, and incorporate outcome measures capable of detecting meaningful internal shifts not always evident through observable behaviour.

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Appendix A – Prisma Checklist

Section	Item	Checklist Item	Status	Location in Review
Title	1	Identify the report as a systematic review.	Yes	Title Page
Abstract	2	Provide a structured summary.	Yes	Abstract
Introduction	3	Rationale for the review.	Yes	Introduction (1.0)
	4	Explicit statement of the objectives or research questions.	Yes	Section 1.1
Methods	5	Eligibility criteria.	Yes	Section 2.1
	6	Information sources.	Yes	Section 2.2
	7	Search strategy (full strategy reported or in appendix).	Yes	Appendix B
	8	Selection process (who screened, how, and how many).	Yes	Section 2.3
	9	Data collection process (how data were extracted).	Yes	Section 2.4

	10a	Data items (outcomes and definitions).	Yes	Section 2.4–2.5
	10b	Other variables collected (e.g. study characteristics).	Yes	Section 2.5
	11	Risk of bias assessment method.	Yes	Section 2.6
	12	Effect measures (if applicable).	N/A	Not applicable (no meta-analysis)
	13a–f	Synthesis methods (grouping, handling heterogeneity, etc.).	Yes	Section 2.7 and 3.5
	14	Reporting bias assessment.	Yes	Section 3.6
	15	Certainty assessment (e.g. GRADE).	No	Not used (noted in limitations)
Results	16a	Number of studies screened and included.	Yes	Section 3.1, PRISMA Flow Diagram
	16b	Reasons for exclusion.	Yes	PRISMA Flow Diagram and 2.3
	17	Characteristics of included studies.	Yes	Table 1
	18	Risk of bias in included studies.	Yes	Table 2 and 3.4
	19	Results of individual studies.	Yes	Section 3.5
	20a–d	Results of syntheses.	Yes	Sections 3.5–3.6
	21	Reporting bias – outcome-level.	Yes	Noted in 3.6
	22	Certainty of evidence	Yes	Sections 3.6 & 4.0
Discussion	23a	Summary of main findings.	Yes	Section 4.0, opening
	23b	Strengths and limitations of evidence.	Yes	Sections 4.2–4.3
	23c	Limitations of the review process.	Yes	Section 3.6.3 & 4.3
	23d	Implications for practice/research.	Yes	Section 4.4
Other information	24a	Registration and protocol.	Yes	Registration stated in 2.1
	24b	Protocol amendments.	N/A	No amendments
	25	Support/funding.	Yes	Acknowledgements
	26	Competing interests.	Yes	Acknowledgements
	27	Availability of data/material.	Yes	Appendices

Appendix B – Search Strategy

PsychInfo

1. exp Affective Psychosis/ or exp Paranoid Psychosis/ or exp Chronic Psychosis/ or exp Psychosis/

2. psychos#s.ti,ab.

3. exp Schizophrenia/ or exp Acute Schizophrenia/ or exp Paranoid Schizophrenia/

4. schizo*.ti,ab.

5. 1 or 2 or 3 or 4

6. exp Exercise/ or exp Aerobic Exercise/

7. exp Sports/

8. exp Physical Activity/

9. (physical* adj5 (activ* or condition* or train* or fit*)).tw.

10. (exercis* or aerobic or anaerobic or endurance* or resistance* or strength* or stamina or treadmill).tw.

11. (baseball or basketball or bicycl* or boxing or climbing* or cricket or cycling or football or golf or gym* or hockey or jog* or martial or mountaineering or rowing or rugby or run* or skating or skiing or soccer or football or sport* or squash or swim* or tennis or triathlon or volleyball or walk* or (water adj1 sport*) or weight lifting or wrestling).tw.

12. 6 or 7 or 8 or 9 or 10 or 11

13. exp Intrinsic Motivation/ or exp Motivation Measures/ or exp Motivation/ or exp Extrinsic Motivation/

14. (PANSS or CAINS or IMI-SR or GCOS or MAP-SR or SEDS or SENS or SANS or BNSS or AES-C or BREQ* or POMS or K-PASE or SIMPAQ or EMI-2 or IPAQ or actigrap* or Pedometer or accelerometer).tw.

15. (accelerometer or pedometer or accelerometry or actimetry or wearable computer or activity tracker).tw.

16. (activity monitor* or activity tracker* or acceleromet* or pedomet* or wearable* or fitness tracker* or fitness monitor* or step count* or step-based or fitbit or apple watch or garmin or samsung or jawbone or polar or nike fuelband or withings or actigraph).tw.

17. (Motivat* or Avolit* or Amotivation or Apathy or Demotivat*).tw.

18. ((Intrinsic* or extrinsic* or controlled or autonomous or identified or integrated or approach or avoidance) adj Motiv*).tw.

19. (Self-Determ* or SDT).tw.

20. (Sedentary adj (behave* or time)).tw.

21. Negative Symptom*.tw.

22. 13 or 14 or 17 or 18 or 19 or 20 or 21

23. 5 and 12 and 22

24. limit 23 to english language

25. limit 24 to "remove medline records"

26. limit 25 to yr="2010 -Current"

Medline

1. exp "Schizophrenia Spectrum and Other Psychotic Disorders"/

2. psychos#s.ti,ab.

3. schizo*.ti,ab.

4. 1 or 2 or 3

5. exp Exercise/

6. exp Sports/

7. (physical* adj5 (activ* or exercis* or condition* or train* or fit*)).tw.

8. (exercis* or aerobic or anaerobic or endurance* or resistance* or strength* or stamina or treadmill).tw.

9. (baseball or basketball or bicycl* or boxing or climbing* or cricket or cycling or football or golf or gym* or hockey or jog* or martial or mountaineering or rowing or rugby or run* or skating or skiing or soccer or sport* or squash or swim* or tennis or triathlon or volleyball or walk* or (water adj1 sport*) or weight lifting or wrestling).tw.

10. 5 or 6 or 7 or 8 or 9

11. exp Motivation/

12. (PANSS or CAINS or IMI-SR or GCOS or MAP-SR or SEDS or SENS or SANS or BNSS or AES-C or BREQ* or POMS or K-PASE or SIMPAQ or EMI-2 or IPAQ).tw.

13. (accelerometer or pedometer or accelerometry or actimetry or wearable computer or activity tracker).tw,kw.

14. (activity monitor* or activity tracker* or acceleromet* or pedomet* or wearable* or fitness tracker* or fitness monitor* or step count* or step-based or fitbit or apple watch or garmin or samsung or jawbone or polar or nike fuelband or withings or actigraph).tw,kw.

15. (Motivat* or Avolit* or Amotivation or Apathy or Demotivat*).tw.

16. ((Intrinsic* or extrinsic* or controlled or autonomous or identified or integrated or approach or avoidance) adj Motiv*).tw.

17. (Self-Determ* or SDT).tw.

18. (Sedentary adj (behave* or time)).tw.

19. Negative Symptom*.tw.

20. 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19

21. 4 and 10 and 20

22. limit 21 to (english language and humans and yr="2010 -Current")

Embase

1. exp psychosis/

2. psychos#s.ti,ab.

3. schizo*.ti,ab.

4. 1 or 2 or 3

5. exp physical activity/

6. exp exercise/

7. exp sport/

8. (physical* adj5 (activ* or exercis* or condition* or train* or fit*)).tw.

9. (exercis* or aerobic or anaerobic or endurance* or resistance* or strength* or stamina or treadmill).tw.

10. (baseball or basketball or bicycl* or boxing or climbing* or cricket or cycling or football or golf or gym* or hockey or jog* or martial or mountaineering or rowing or rugby or run* or skating or skiing or soccer or sport* or squash or swim* or tennis or triathlon or volleyball or walk* or (water adj1 sport*) or weight lifting or wrestling).tw.

11. 5 or 6 or 7 or 8 or 9 or 10

12. exp motivation/

13. exp negative syndrome/

14. (PANSS or CAINS or IMI-SR or GCOS or MAP-SR or SEDS or SENS or SANS or BNSS or AES-C or BREQ* or POMS or K-PASE or SIMPAQ or EMI-2 or IPAQ).tw.

15. (accelerometer or pedometer or accelerometry or actimetry or wearable computer or activity tracker).tw,kw.

16. (activity monitor* or activity tracker* or acceleromet* or pedomet* or wearable* or fitness tracker* or fitness monitor* or step count* or step-based or fitbit or apple watch or garmin or samsung or jawbone or polar or nike fuelband or withings or actigraph).tw,kw.

17. (activity monitor* or activity tracker* or acceleromet* or pedomet* or wearable* or fitness tracker* or fitness monitor* or step count* or step-based or fitbit or apple watch or garmin or samsung or jawbone or polar or nike fuelband or withings or actigraph).tw,kw.

18. (Motivat* or Avolit* or Amotivation or Apathy or Demotivat*).tw.

19. ((Intrinsic* or extrinsic* or controlled or autonomous or identified or integrated or approach or avoidance) adj Motiv*).tw.

20. (Self-Determ* or SDT).tw.

21. (Sedentary adj (behav* or time)).tw.

22. Negative Symptom*.tw.

23. 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22

24. 4 and 11 and 23

25. limit 24 to (human and english language and "remove medline records" and yr="2010 - Current")

Appendix C – SCRIBE 2016 Checklist

Checklist Item	Status	Location
1. Title and Abstract	Yes	Title Page and Abstract
2. Rationale	Yes	1.0 Introduction and 1.1 Aims and Research Questions
3. Participant Characteristics	Yes	2.2 Participants
4. Setting: Setting described as NHS inpatient rehabilitation units.	Yes	2.2 Participants
5. Dependent Variables: Motivation measured via CAINS, IMI-SR, and physical activity monitors.	Yes	2.4 Measures
6. Independent Variable: Intervention is described as modular and mechanistically targeted.	Yes	2.3 Intervention

7. Experimental Design: Multiple baseline SCED across participants is explained.	Yes	2.1 Design
8. Baseline: Description of baseline phases and durations included.	Yes	2.5 Procedure
9. Blinding: Not explicitly mentioned; may not be feasible in this design.	No	4.1 Limitations
10. Inter-observer Agreement: Not reported for outcome measures.	No	4.1 Limitations
11. Fidelity: No specific fidelity checks reported.	No	4.1 Limitations
12. Data Analysis: Visual analysis described; no statistical analysis planned.	Yes	2.6 Data Analysis
13. Results: Individual outcomes described with figures and narrative synthesis.	Yes	3.0 Results
14. Discussion: Interpretation and limitations discussed in detail.	Yes	4.0 Discussion
15. Ethical Approval: REC reference and GDPR compliance stated.	Yes	2.2.4 Recruitment & Consent Procedure

Appendix D – Final Approved MRP Proposal

https://osf.io/mt8w7/files/osfstorage

Appendix E – Proceed to Ethics

University of Glasgow

School of Health & Wellbeing

BC/PR

30th January 2024

Zachary Barry

Dear Zachary,

Major Research Project Proposal

Exploring the effect of a novel psychological intervention for negative symptoms based on transdiagnostic mechanisms of change

The above project has been reviewed by your University Research Supervisor and by a member of staff not involved in your project and has now been deemed fit to proceed to ethics.

Congratulations and good luck with the study.

Yours sincerely

Dr Breda Cullen
Senior Lecturer in Clinical Psychology
DClinPsy Research Director

School of Health & Wellbeing
College of Medical, Veterinary and Life Sciences
University of Glasgow
Mental Health and Wellbeing, Clarice Pears Building
90 Byres Road, Glasgow G12 8TB
Email: dclinpsy@glasgow.ac.uk

Appendix F – Ethics Approval

NHS
Health Research Authority

South West - Cornwall & Plymouth Research Ethics Committee
2 Redman Place
Stratford
London
E20 1JQ

Telephone: 0207 104 8079

07 August 2024

Professor Hamish McLeod
University of Glasgow
Clarice Pears Building
90 Byres Road
G128TB

Dear Professor McLeod

Study title:	**Exploring the effect of a novel psychological intervention for negative symptoms based on transdiagnostic mechanisms of change.**
REC reference:	**24/SW/0084**
IRAS project ID:	**340016**

Thank you for your letter of 02 August 2024, responding to the Research Ethics Committee's (REC) request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair and Miss Sue Evans.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Good practice principles and responsibilities

The UK Policy Framework for Health and Social Care Research sets out principles of good practice in the management and conduct of health and social care research. It also outlines the responsibilities of individuals and organisations, including those related to the four elements of research transparency:

1. registering research studies
2. reporting results
3. informing participants
4. sharing study data and tissue

A Research Ethics Committee established by the Health Research Authority

Conditions of the favourable opinion

The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

Confirmation of Capacity and Capability (in England, Northern Ireland and Wales) or NHS management permission (in Scotland) should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for HRA and HCRW Approval (England and Wales)/ NHS permission for research is available in the Integrated Research Application System.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations

Registration of Clinical Trials

All research should be registered in a publicly accessible database and we expect all researchers, research sponsors and others to meet this fundamental best practice standard.

It is a condition of the REC favourable opinion that **all clinical trials are registered** on a public registry before the first participant is recruited and no later than six weeks after. For this purpose, 'clinical trials' are defined as:

- clinical trial of an investigational medicinal product
- clinical investigation or other study of a medical device
- combined trial of an investigational medicinal product and an investigational medical device
- other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice.

A 'public registry' means any registry on the WHO list of primary registries or the ICMJE list of registries provided the registry facilitates public access to information about the UK trial.

Failure to register a clinical trial is a breach of these approval conditions, unless a deferral has been agreed by the HRA (for more information on registration and requesting a deferral see: Research registration and research project identifiers).

Where a deferral is agreed we expect the sponsor to publish a minimal record on a publicly accessible registry. When the deferral period ends, the sponsor should publish the full record on the same registry, to fulfil the condition of the REC favourable opinion.

If you have not already included registration details in your IRAS application form you should notify the REC of the registration details as soon as possible.

Where the study is registered on ClinicalTrials.gov, please inform deferrals@hra.nhs.uk and the Research Ethics Committee (REC) which issued the final ethical opinion so that our records can be updated.

Publication of Your Research Summary

We will publish your research summary for the above study on the research summaries section of our website, together with your contact details, no earlier than three months from the date of this favourable opinion letter. Where a deferral is agreed, a minimum research summary will still be published in the research summaries database. At the end of the deferral period, we will publish the full research summary.

Should you wish to provide a substitute contact point, make a request to defer, or require further information, please visit: Research summaries - Health Research Authority (hra.nhs.uk)

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

After ethical review: Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study, including early termination of the study
- Final report
- Reporting results

The latest guidance on these topics can be found at Managing your approval - Health Research Authority (hra.nhs.uk)

Ethical review of research sites

NHS/HSC sites

The favourable opinion applies to all NHS/HSC sites taking part in the study, subject to confirmation of Capacity and Capability (in England, Northern Ireland and Wales) or management permission (in Scotland) being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Non-NHS/HSC sites

I am pleased to confirm that the favourable opinion applies to any non-NHS/HSC sites listed in the application, subject to site management permission being obtained prior to the start of the study at the site.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	*Version*	*Date*
Covering letter on headed paper [Cover Letter REC Response]	1.0	02 August 2024

Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Insurance/ Indemnity Letter]		14 June 2023
Interview schedules or topic guides for participants [Guide for Verbal Feedback]	1.0	10 June 2024
IRAS Application Form [IRAS_Form_18062024]		18 June 2024
Participant consent form [Consent Form]	1.0	10 June 2024
Participant information sheet (PIS) [Privacy Notice]	1.0	10 June 2024
Participant information sheet (PIS) [Participant Information Sheet]	2.0	02 August 2024
Research protocol or project proposal [Research Protocol]	1.0	10 June 2024
Summary CV for Chief Investigator (CI) [CI CV]		01 December 2023
Summary CV for student [Student CV]		05 February 2024
Summary CV for supervisor (student research) [Supervisor CV]		01 December 2023
Validated questionnaire [Clinical Assessment Interview for Negative Symptoms]		
Validated questionnaire [Montreal Cognitive Assessment]		
Validated questionnaire [Intrinsic Motivation Inventory: Schizophrenia Research]		
Validated questionnaire [Client Satisfaction Questionaire-18]		

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: Quality assurance - Health Research Authority (hra.nhs.uk)

HRA Learning

We are pleased to welcome researchers and research staff to our HRA Learning Events and online learning opportunities– see details at: Learning - Health Research Authority (hra.nhs.uk)

IRAS project ID: 340016 Please quote this number on all correspondence

With the Committee's best wishes for the success of this project.

Yours sincerely
Pp

Dr Stephen Coles
Chair

Email:cornwallandplymouth.rec@hra.nhs.uk

Enclosures: **Non CTIMP Standard Conditions of Approval**

A Research Ethics Committee established by the Health Research Authority

File Note

Study Title / Acronym	Transdiagnostic treatment for negative symptoms
R&D Ref:	GN24MH268 **Date Prepared:** 10/02/25
Site:	Stobhill NHS GG&C

Description of Issue:

Give a brief description of the issue(s) including the reason(s) for it happening

We need to recruit one additional participant to meet the minimum number required of the proposed SCED (3). We had a participant but they dropped out before we had a chance to collect meaningful data.

The current proposed treatment intervention is 17~ weeks. That does not give us enough time to complete the data collection before 25/05/25 which is our data gathering deadline. Therefore, we will offer a new participant (who is known to the researchers and has expressed an interest) a condensed treatment package. This will involve offering the person a few weeks with two treatment sessions in rather than one. This is a fairly normal accommodation in psychological clinical practice when there is an unforeseen deadline (eg. the person is moving to a different area, the clinician is changing job etc.). The treatment content will stay exactly the same as documented in the Study Protocol. The participants experience of the treatment will be materially the same as the participants in the non-condensed treatment.

Corrective Actions Taken:

List all actions taken to address the issue(s)

Explain clearly to the participant that they will be offered some weeks with double sessions. Ensure this is understood prior to their consent being given.

Record this clearly in the medical notes.

Make a note in the person's research file.

Intervention facilitator to check with patient on the week there is due to be a double session, record this in medical notes.

This has been discussed with the sponsor representative on 10/02/2025.

Preventative Actions Taken:

Describe what measures have been put in place to ensure the issue does not happen again or explain why preventative measures are not applicable

Not applicable as we're only recruiting one additional participant.

Copy to: Mrs Shirley Mitchell, University of Glasgow

Lead Nation Scotland: gram.nrspcc@nhs.scot

Prepared by:	Z.barry	**Position:**	Researcher
Signature:	zb	**Date:**	10/02/25
Reviewed by:	S K Mitchell	**Position:**	Sponsor Representative
Signature:		**Date:**	11/02/2025

Appendix H – Participant Information Sheet & Consent Form

https://osf.io/mt8w7/files/osfstorage

Appendix I – Analysis Plan

https://osf.io/mt8w7/files/osfstorage

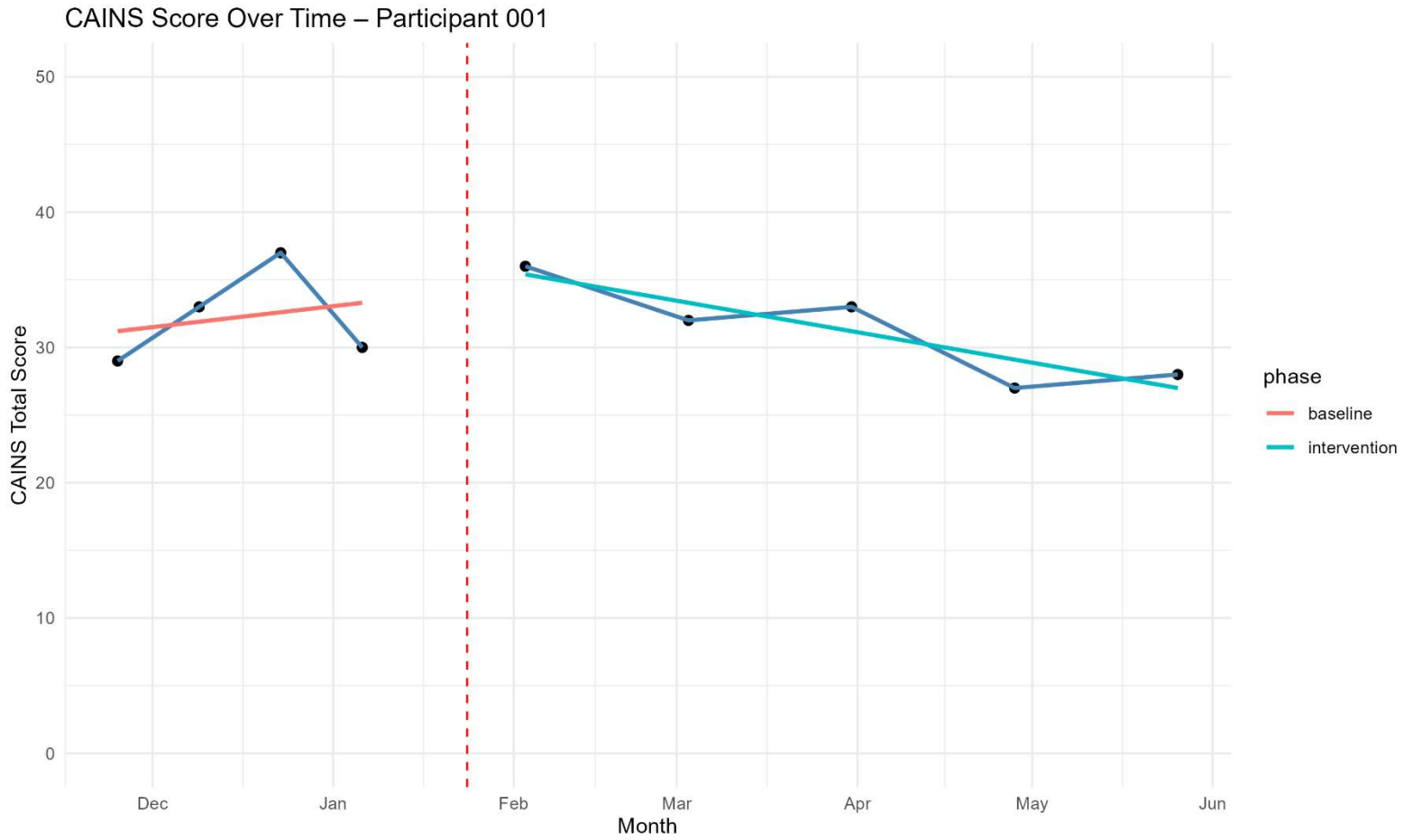
Appendix J – R Code

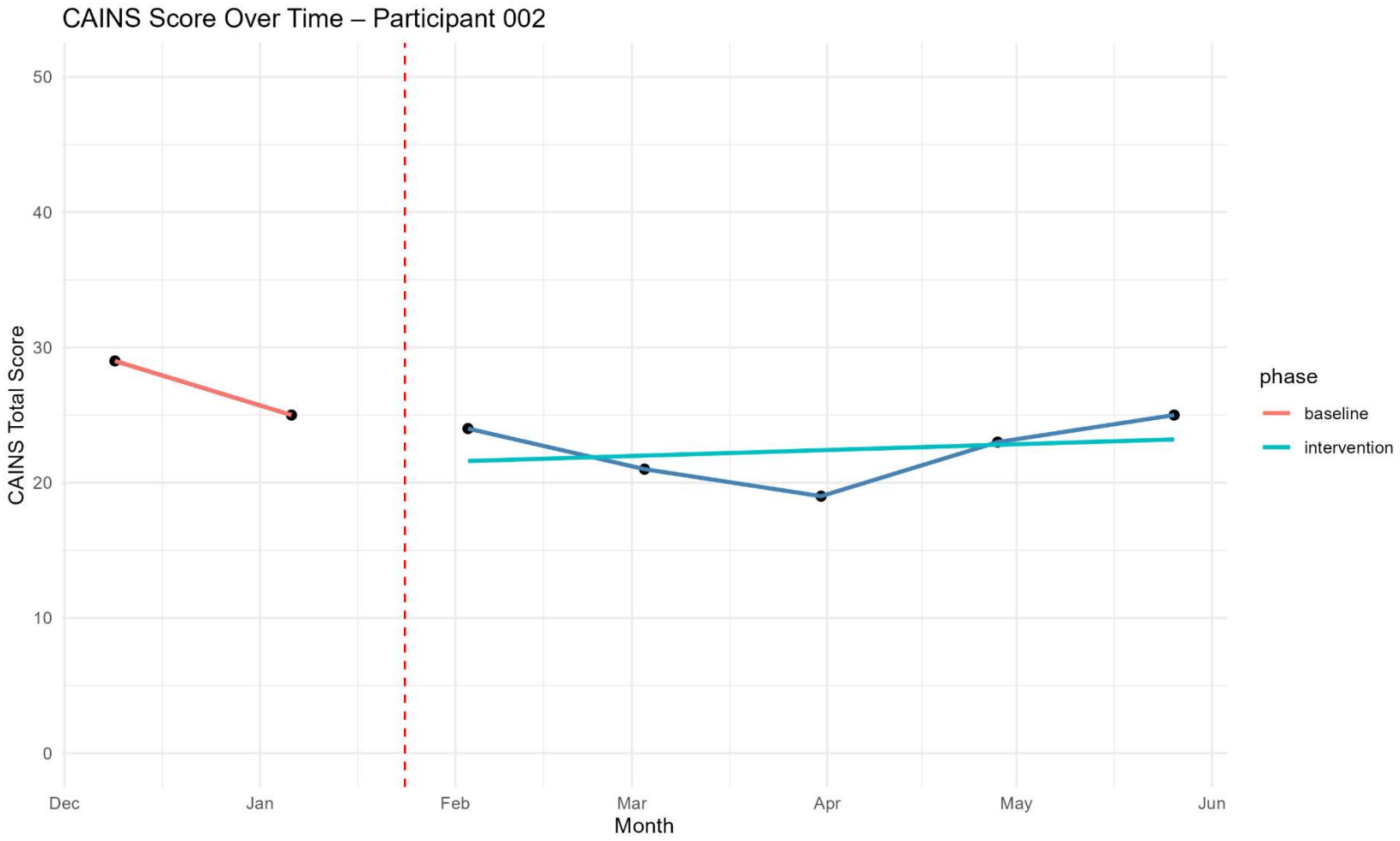
https://osf.io/mt8w7/files/osfstorage

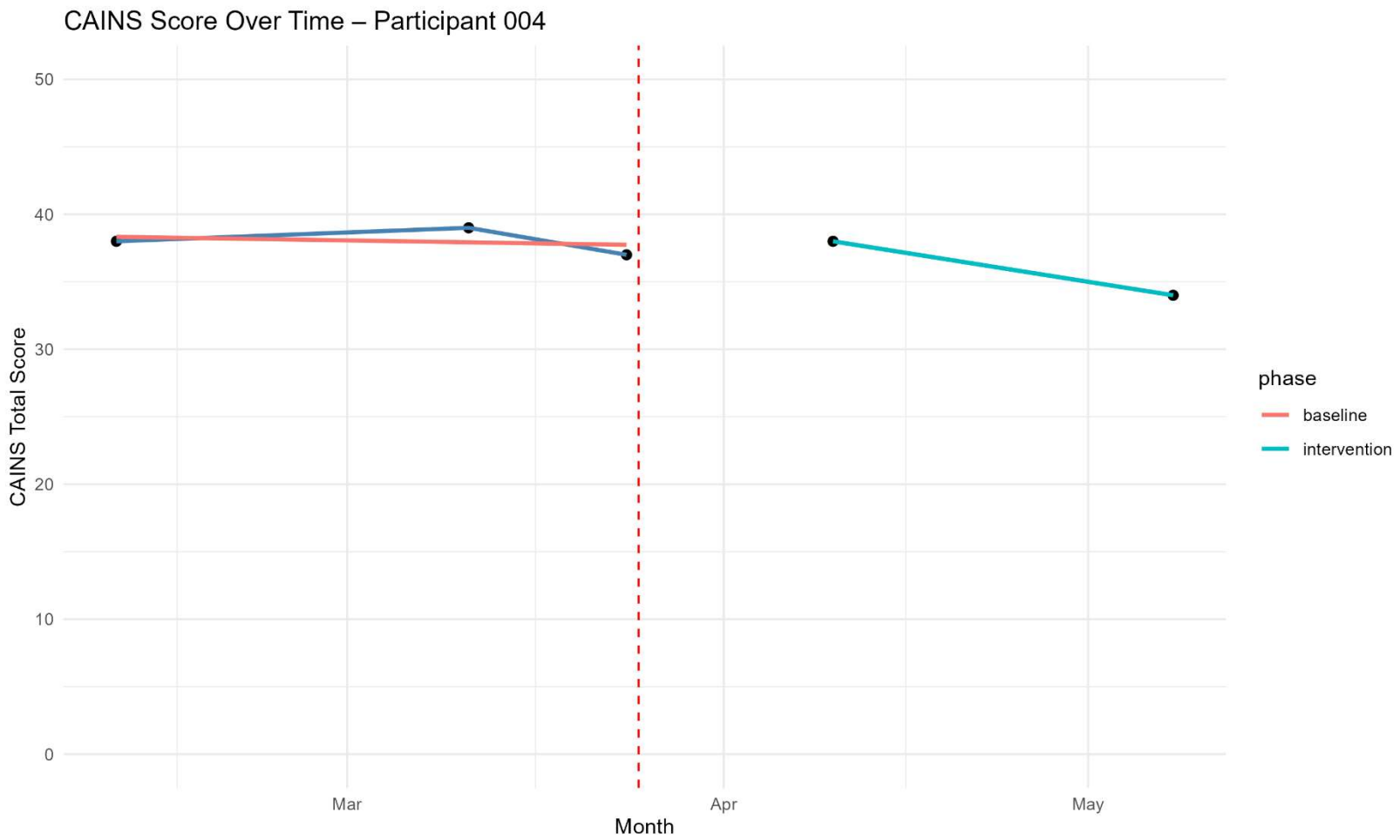
Appendix K – Data Availability Statement

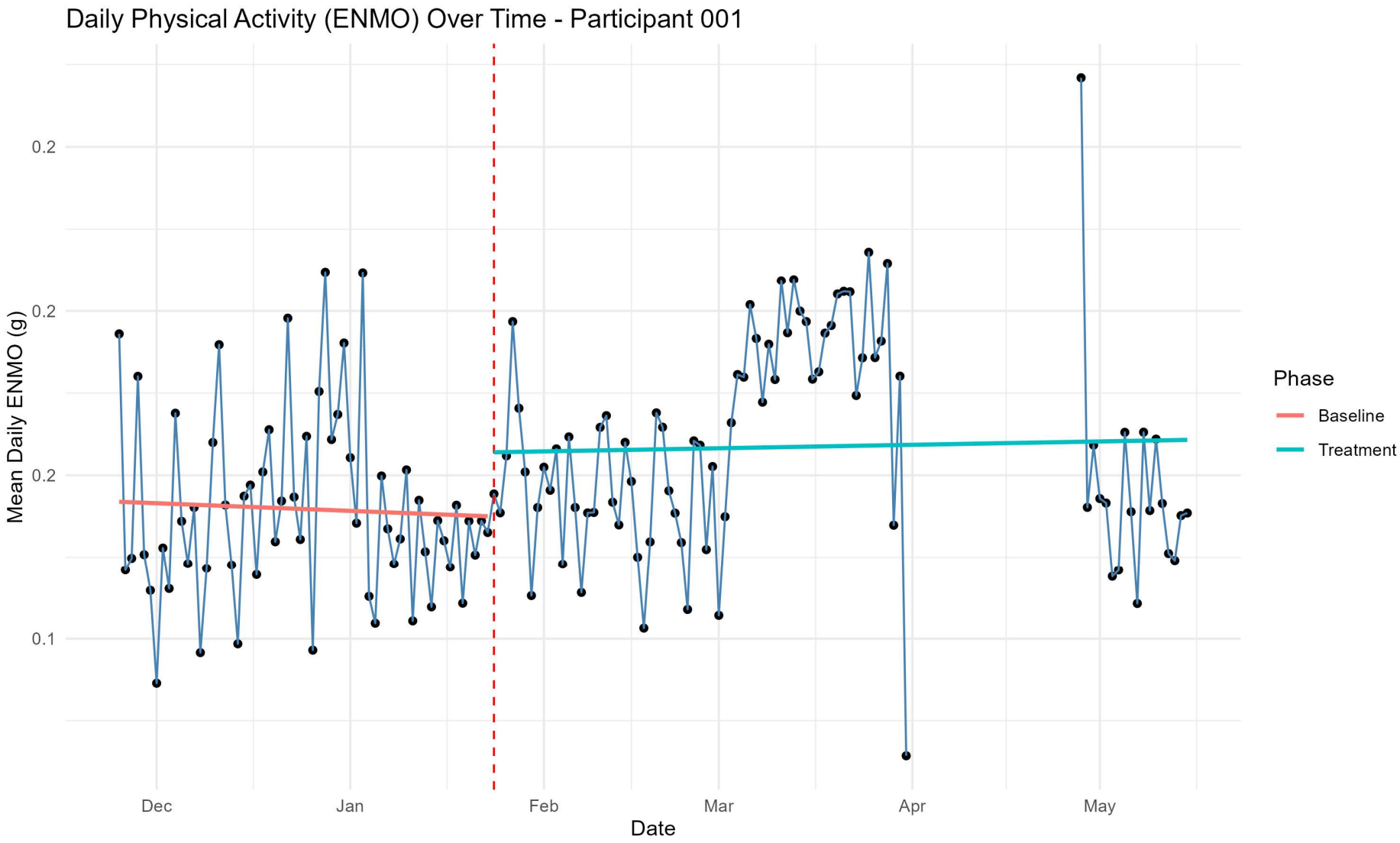
Anonymised electronic data will be stored on the University of Glasgow's institutional repository, Enlighten, for a minimum of 10 years in accordance with University research data retention policies.

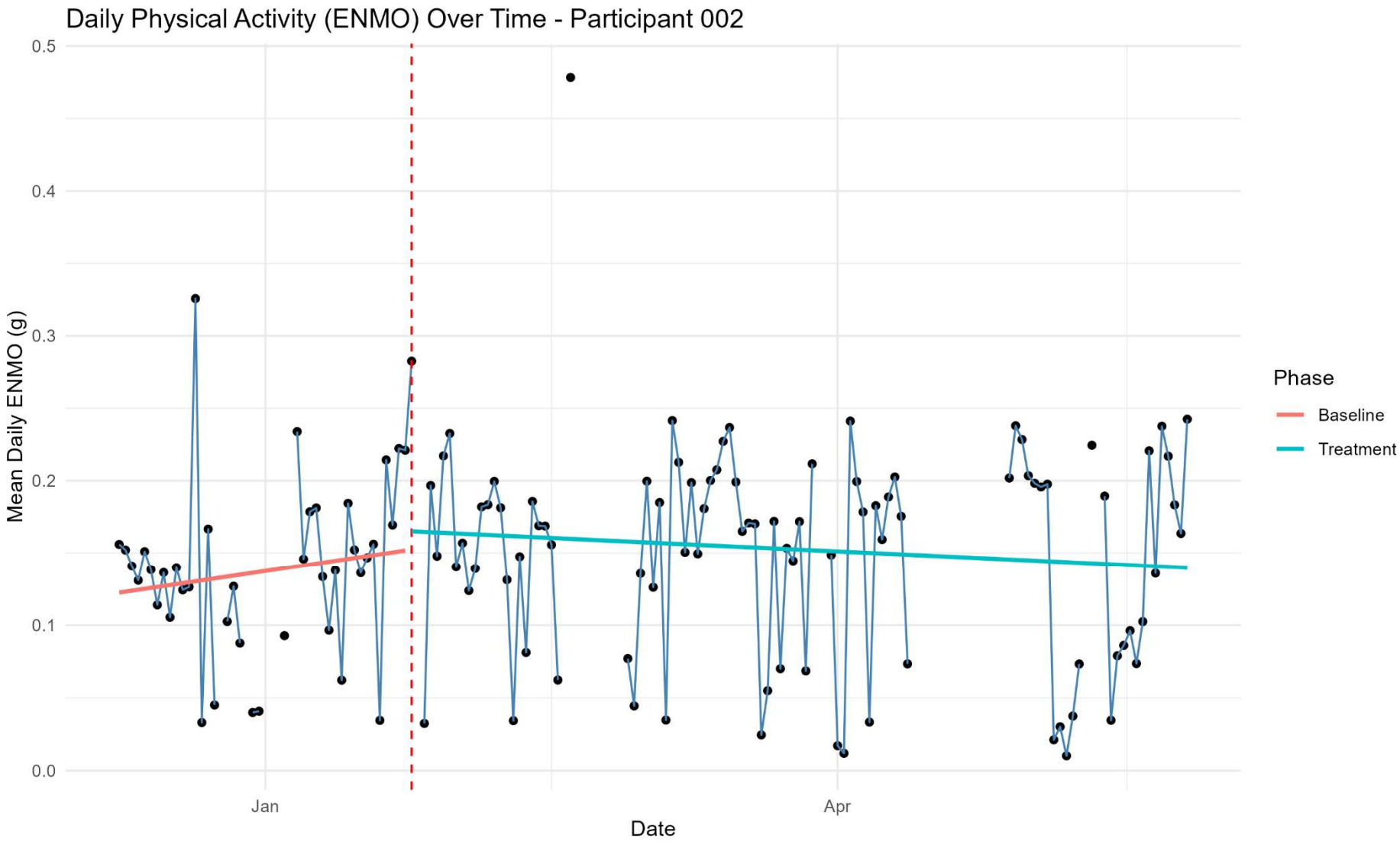
Appendix L – Supplementary Data CAINS

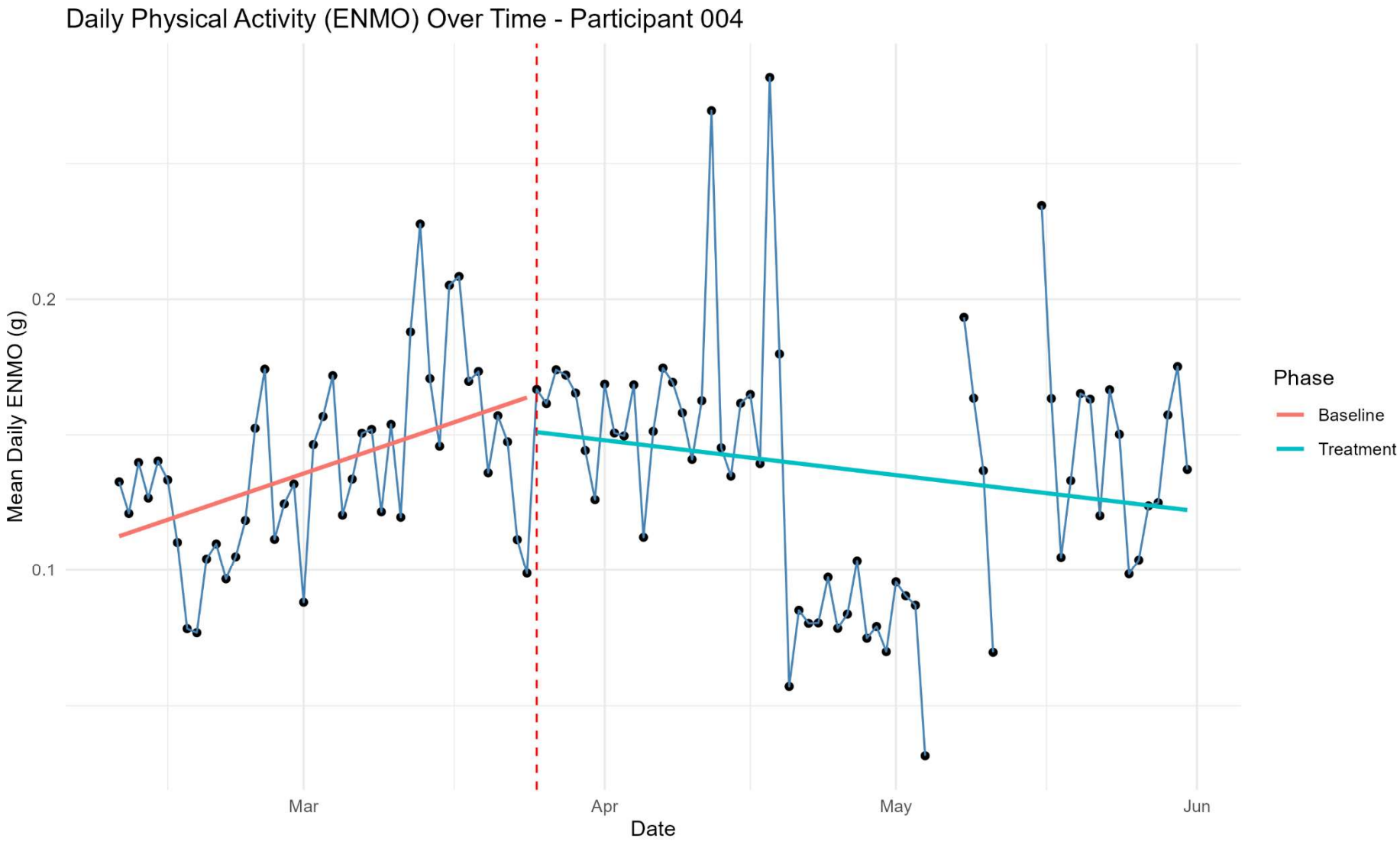



CAINS Score Over Time – Participant 002
CAINS Total Score
50
40
30
20
10
0
Dec
Jan
Feb
Mar
Apr
May
Jun
Month
phase
baseline
intervention

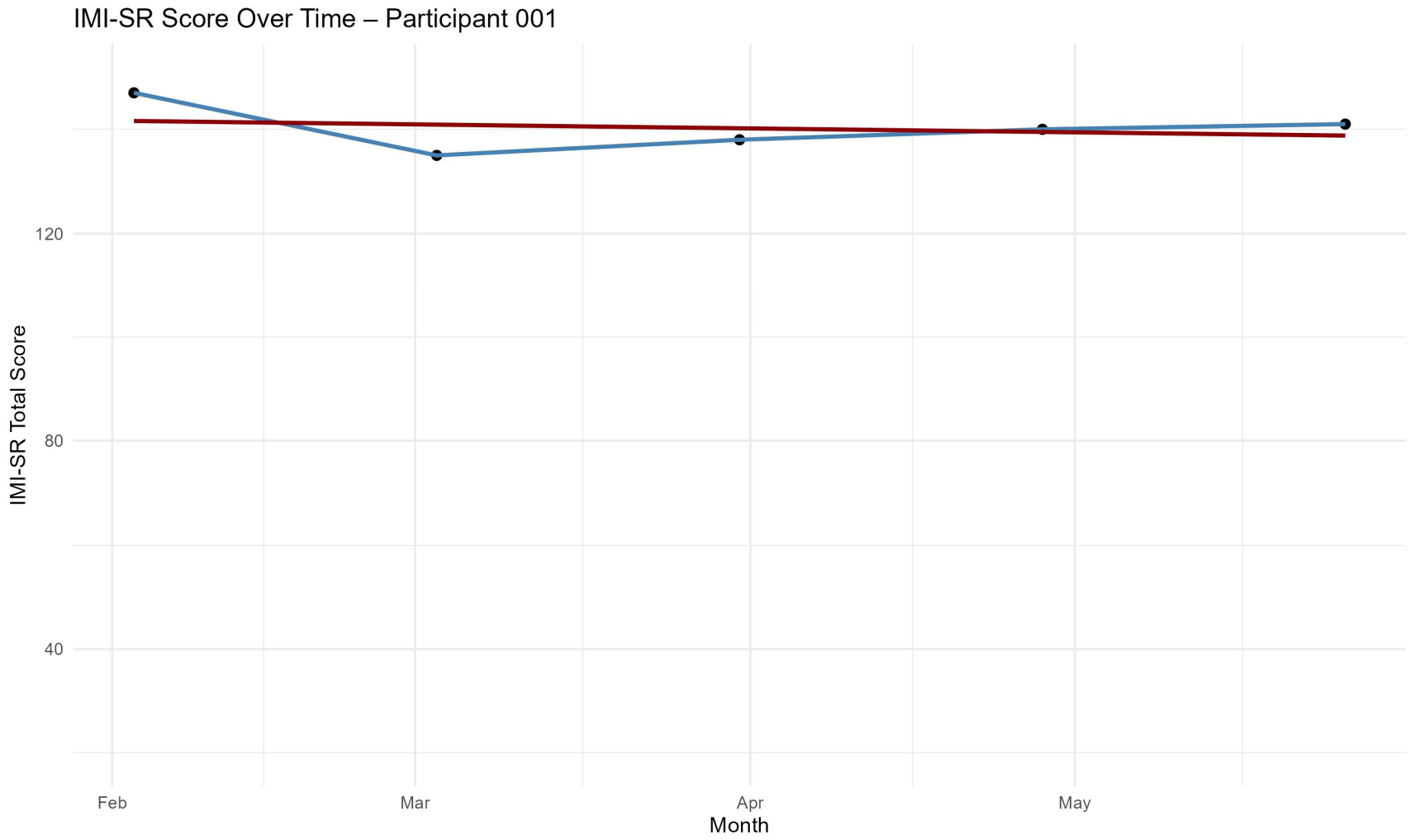

CAINS Score Over Time – Participant 004
CAINS Total Score
50
40
30
20
10
0
Mar
Apr
May
Month
phase
baseline
intervention

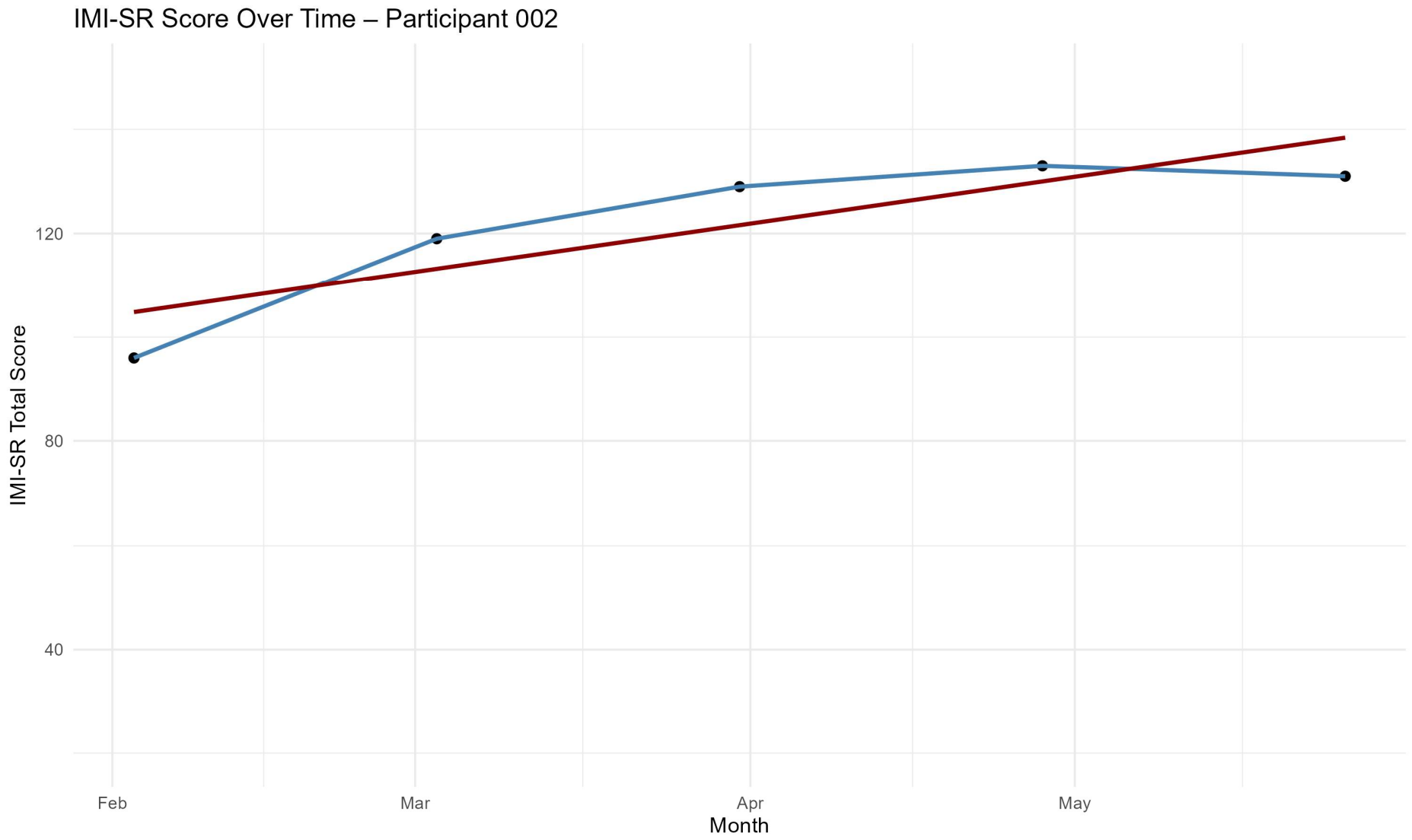

Daily Physical Activity (ENMO) Over Time - Participant 001
Mean Daily ENMO (g)
0.2
0.2
0.2
0.1
Dec
Jan
Feb
Mar
Apr
May
Date
Phase
Baseline
Treatment

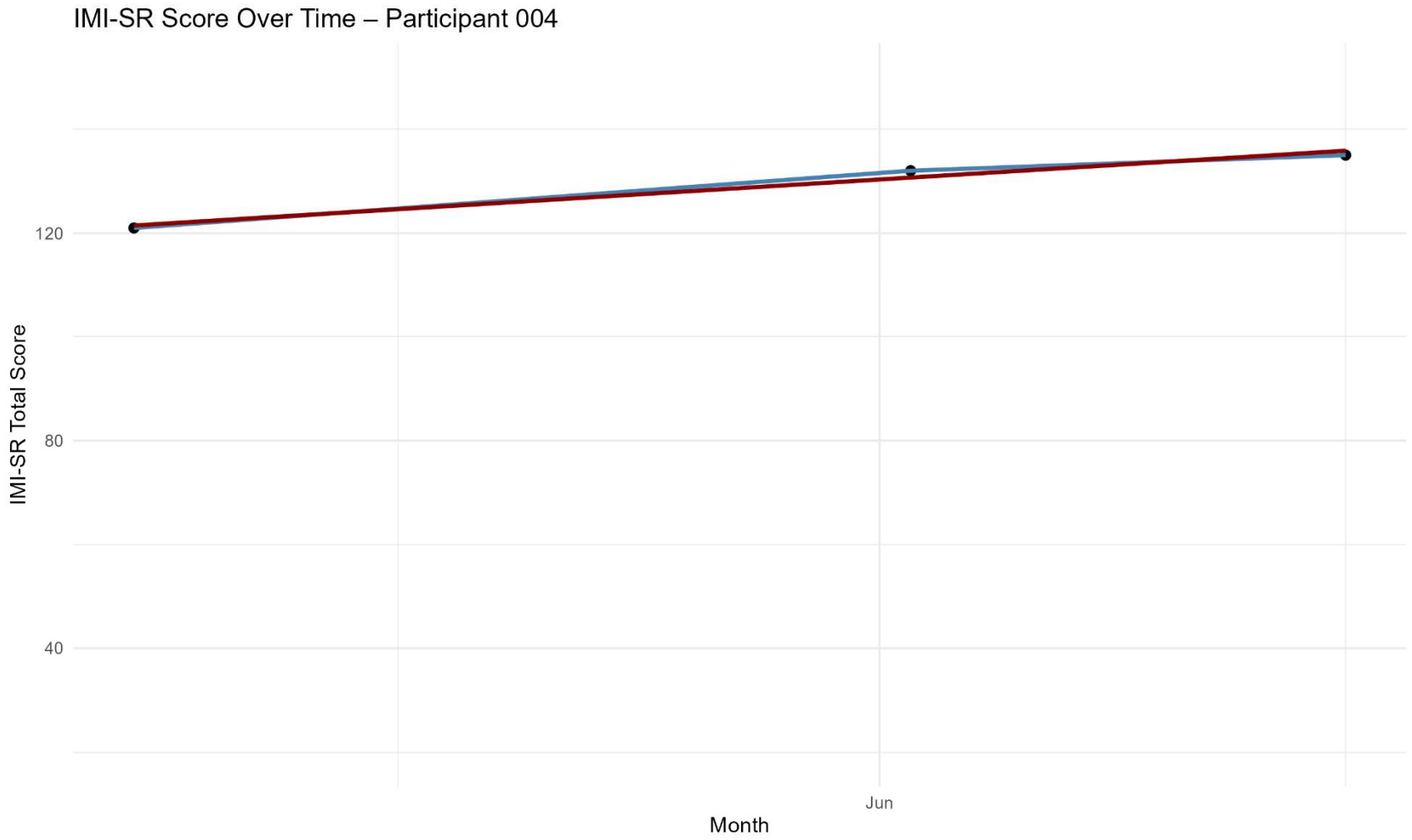

Daily Physical Activity (ENMO) Over Time - Participant 002
Mean Daily ENMO (g)
0.5
0.4
0.3
0.2
0.1
0.0
Jan
Apr
Date
Phase
Baseline
Treatment


Daily Physical Activity (ENMO) Over Time - Participant 004
Mean Daily ENMO (g)
0.2
0.1
Mar
Apr
May
Jun
Date
Phase
Baseline
Treatment

Appendix N – Supplementary Data IMI-SR




IMI-SR Score Over Time – Participant 002
IMI-SR Total Score
120
80
40
Feb
Mar
Apr
May
Month


IMI-SR Score Over Time – Participant 004
IMI-SR Total Score
120
80
40
Jun
Month

Appendix O - TIDieR

TIDieR Checklist – Template for Intervention Description and Replication

Adapted from: Hoffmann, T. C., Glasziou, P. P., Boutron, I., Milne, R., Perera, R., Moher, D., ... & Michie, S. (2014). Better reporting of interventions: Template for intervention description and replication (TIDieR) checklist and guide. BMJ, 348, g1687. https://doi.org/10.1136/bmj.g1687

TIDieR Item	Your Intervention Details
1. Brief Name Provide the name or a descriptive phrase for the intervention.	Targeting of Psychosocial Treatments in Psychosis (ToPTiP)
2. Why (Rationale) Describe the rationale, theory, or goal of the intervention and why it should work.	The intervention targets negative symptoms in schizophrenia by focusing on transdiagnostic mechanisms such as reduced anticipatory pleasure, low intrinsic motivation, and maladaptive cognitive appraisals. It integrates elements of behavioural activation, cognitive behavioural therapy, and motivational enhancement to address these underlying processes. The goal is to improve motivation, increase engagement in rewarding activities, and enhance functional outcomes. By tailoring modules to individual profiles and targeting mechanisms directly, the intervention aims to achieve greater effectiveness than standard approaches.
3. What (Materials) Describe all materials used in the intervention, such as manuals, handouts, worksheets, or tools.	The structure of the intervention was guided by a published summary of mechanisms of change in psychological therapies for negative symptoms (McLeod, 2022) and supplemented by additional therapy notes and materials based on the current literature addressing the psychological factors involved in the development and maintenance of negative symptoms. Summary handouts and personalised depictions of key therapy learning points were developed for each patient as treatment progressed. Assessment of key causal and maintenance

	mechanisms was conducted with published scales (e.g. BCSS).
4. What (Procedures) Outline all procedures, activities, and/or processes used during the intervention, step by step.	Included is a detailed explanation of different modules within the intervention. Engagement and Goal Setting Key topics and targets: • Exploration of preferred therapy format and intensity • Discussion of neutral topics and interests • Exploring goals, values, and sources of meaning • Review of past goal setting experiences and successful goal completion • Discussion of intrinsic versus extrinsic motivation • Setting SMART goals that are linked to sources of personal meaning Effort Expenditure and Goal Pursuit Key topics and targets: • Imagining outcomes in the future • Mental traps that affect how we set and pursue goals • Balancing decisions using effort-reward payoffs • Strategies for refocusing on valued outcomes • Anticipating pleasurable experiences • Maximising "in the moment" pleasure Social and Interpersonal Skills Key topics and targets: • Understanding social fears and worries • Reducing excessive self-focused attention • Decoding facial expressions • Sending effective social signals • Using graded social demands to build confidence

	### Addressing Cognitive Difficulties
	Key topics and targets:
	• Understanding thinking skills
	• Types of memory and how to improve encoding and recall
	• Managing wandering attention and difficulties with concentration
	• Problem solving skills and dealing with complexity
	• Changing the environment to help support thinking skills
	
	### Addressing Meta-Cognitive Difficulties
	Key topics and targets:
	• Awareness of own mind
	  ○ Recognition and naming of different mental operations
	  ○ Differentiation of mental experiences – cognition, emotion, compound states
	  ○ Recognition of changes in mental experience over time
	  ○ Recognition of the fallibility of thoughts and inferences
	• Awareness of other's minds
	  ○ Understanding that others are motivated by factors such as thoughts, emotions, and learning history
	  ○ Understanding that the behaviour of others may vary across different contexts/settings
	  ○ Using social cues (e.g. facial expressions) and knowledge of people over time can help build social relationships
	  ○ Re-connecting with social contacts often take time but is worth it
	• Meaning and values
	  ○ Social confidence can be hard to re-build - is the discomfort is worth it?
	  ○ You can influence social relationships (e.g.

	addressing pervasive fears of non-acceptance) ○ Understanding the difference between goals and values • Short term vs long time frame personal narratives ○ Memories and views of others can be biased by recency effects ○ We are more that the messages we have received from others ○ Our biology (e.g. drive and pleasure seeking) is shaped by our behavioural choices over time – we can get into and out of productive habits • Facing challenges with other people ○ Knowing how to ask for help ○ Giving help and support to others ○ Making connections in social systems
5. Who Provided Describe who delivered the intervention, including qualifications, expertise, and training.	Hamish McLeod Clinical Psychologist Professor of Clinical Psychology
6. How Describe the modes of delivery (e.g. face-to-face, online, individual, group).	Face to Face
7. Where Describe the setting where the intervention was delivered (e.g. clinic, community centre, participant's home).	In-patient setting
8. When and How Much Provide details of the number of sessions, their schedule, duration, intensity, and overall intervention length.	Weekly session offered over 17 weeks, one session offered per week.
9. Tailoring If the intervention was adapted or	Intervention is flexibly configured for each participant. Therefore, all

personalised, describe what, why, when, and how.	interventions are personalised towards the specific needs of the individual.
10. Modifications Describe any modifications to the intervention that occurred during the study and why they were made.	Nil
11. How Well (Planned) Describe any strategies used to assess or maintain fidelity/adherence to the intervention as planned.	Clinical supervision sessions and case review of the formulation and application of change techniques was used to monitor adherence to the intervention model and rationale for therapy.
12. How Well (Actual) Describe the actual fidelity/adherence to the intervention and if it was assessed, how closely it was delivered as intended.	Given the early stage of treatment development and testing there was no formal assessment of fidelity using checklists or measures. Case notes and therapy process notes were used to document the actions taken across sessions along with a rationale for the application of techniques based on the clinical formulation.