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"Well-Track": Fitbit Based Physical Activity and Sleep Hygiene Intervention for Early Intervention in Psychosis (EIP) and At-Risk Mental State (ARMS) Service Patients

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Abstract

Background: Compared to the general population, people who are at a high risk of or experience severe mental illness (SMI) such as psychosis, are more likely to have low levels of physical activity, high levels of sedentary behaviour, and sleep problems. **Intervention:** The Well-Track intervention comprises a wearable activity and sleep tracker (Fitbit); one session with mental health service staff providing physical activity and sleep hygiene advice; a brief motivational interview; completing a goal setting workbook; and one or two further engagement, feedback and discussion sessions. **Participants:** Twenty-four participants using an early intervention in psychosis (EIP) or at-risk mental state (ARMS) service completed an eight-week, three session intervention (14 males and 10 females), with an age range of 18 - 61, and average age of 27.75 years. **Methods:** An open-label patient cohort design with no control group. Pre-intervention, 4-week and 8-week intervention assessments using participant self-report measures: Patient Health Questionnaire (PHQ-9) (depression), Warwick–Edinburgh Mental Wellbeing Scale (WEMWBS), and Sleep Conditioning Index (SCI); and clinician measurement of body weight. **Results:** Mean scores showed a significant improvement in PHQ-9 from 9.29 (*SD* 5.89) to 5.58 (*SD* 3.68) at 4 weeks and to 5.83 (*SD* 4.40) at 8 weeks, with large effect sizes. For those who met a diagnosis of depression at baseline, at 4 week follow-up seven participants (26%) experienced remission and nine (33%) reliable improvement, and at 8 week follow-up four (21%) experienced remission and seven (37%) reliable improvement. WEMWBS scores signifi-

cantly improved, from 44.04 (*SD* 9.44) to 48.54 (*SD* 8.71) at 4 weeks and to 48.67 (*SD* 8.76) at 8 weeks, with large effect sizes. Body weight did not change significantly, remaining unchanged at 4 weeks and reduced from a mean of 82.8 kg (baseline) to 80.15 kg at 8 weeks, a reduction of 2.65 kg. **Conclusion:** Well-Track was integrated into an EIP and ARMS service and was found to be beneficial in terms of wellbeing, depression, sleep, and preventing weight gain (either as a two or three engagement point intervention). Well-Track could be delivered through EIP and ARMS services to promote healthy lifestyle behaviours.

Keywords

Fitbit, Tracker, Psychosis, Exercise, Insomnia, Wearables, Activity

1. Introduction

The phrase 'severe mental illness' (SMI) refers to psychological problems where the ability to engage in functional and occupational activities is severely impaired, for example, psychotic disorders [1]. The prevalence of a psychotic disorder in England is 0.7% of adults aged 16+ [2]. The prevalence of depression in SMI is higher than in the general population, and depending on the phase of the illness can vary from 20% to 60% (for example, rates of 50% are seen in early psychosis) [3].

Levels of physical activity are lower in people who experience SMI than in the general population [4] [5] [6] [7]. Having levels of physical activity that are lower than those recommended [8] can be linked to more depressive symptoms, lower wellbeing, greater hopelessness, lower quality of life, and physical health diseases, including cardiovascular disease (CVD), stroke, hypertension, osteoarthritis, diabetes, and chronic obstructive pulmonary disease (COPD) [9] [10]. Lack of physical activity and poor quality of sleep are contributory factors to the reduced life expectancy in SMI (14.5 years less than the general population) [11]. To address these factors, exercise interventions through mental health services can be effective in aiding recovery [12]. Where depression is present, evidence shows that aerobic exercise can be as effective as taking antidepressant medication or psychotherapy [13] [14] [15], but a lack of interest by many patients in attending organised group-based physical activity interventions offered by mental health services, is a predominant barrier [16].

Sleep problems are common in people at high risk of psychosis and those who experience symptoms of psychosis (with rates of 30% to 80% reported) and they impact negatively on functioning and wellbeing [17] [18] [19] [20]. People with recent experience of psychotic symptoms (delusions and hallucinations) have reported problems getting to sleep, staying asleep, experiencing too little or too much sleep, nightmares, and erratic sleep patterns [21]. Poor sleep in SMI is associated with reduced quality of life, increased suicide risk, cognitive impair-

ment, and worse functioning and symptoms [18] [22] [23] [24] [25] [26]. Severity of sleep disturbance and sleep-related impairment is associated with greater negative mental health symptoms [27].

In SMI, poor sleep initiation (the ability to be able to get to sleep) is common and has a negative impact on individuals' social and occupational functioning [28]. People report that their psychotic experiences are associated with ineffective sleep, and when poor sleep is experienced the consequent tiredness means that they cope less well with hallucinations and persecutory fears, increasing their negative impact on their lives [21]. Patients describe a bidirectional causal relationship between poor quality sleep and severity of psychotic symptom impact [21].

Medication to treat mental illness can cause an increase in body weight; for example, for many people, within three months of commencing some types of antipsychotic medication, there can be rapid increases in body weight [29]. Weight gain in psychosis can also be associated with adverse lifestyle factors, including a sedentary lifestyle and unhealthy food habits [30]. Weight gain can be a cause of distress, reduced self-worth, poor sleep quality, and engaging in less physical activity or exercise [31] [32].

The NHS Long Term Plan and the Mental Health Implementation Long Term Plan 2019/20-2023/24 instigated the setup of 'at-risk mental state' (ARMS) services to provide access to evidence-based care and support for a period of two years [33] [34]. Goals of these services are: the early identification and provision of preventative strategies; delaying or preventing the onset of severe mental health problems; supporting a reduction in the duration of untreated psychosis; providing prompt access to effective treatment if individuals develop distressing psychotic symptoms; quick transferal of people into first episode psychosis care if they do transition to a first episode psychosis; and provision of support for people to live well and maintain good physical health [35]. People meeting the definition for inclusion in ARMS services are more likely to have unhealthy lifestyle behaviours and have poor sleep quality and lower levels of physical activity than the general population [35]. This may be partially due to their experience of negative and disorganised symptoms, cognitive deficits and functional impairment, indicating the need for the development and availability of novel and accessible therapies with an emphasis on improving functioning [36].

Early intervention in psychosis (EIP) services are multidisciplinary community-based mental health teams that assess and treat people within two weeks of a first episode of psychosis, providing a full range of pharmacological, psychological, social, occupational, and educational interventions for up to 3 years [37]. EIP seek to address the 'negative' symptoms of psychosis (such as emotional apathy, lack of drive, poverty of speech, social withdrawal, and self-neglect), and they provide regular physical health checks and monitoring [38]. EIP are required to offer programmes of physical activity [38]; however, there is a lack of physical activity interventions in EIP services that have been found to be effective [39]. When exercise and healthy lifestyle promoting interventions are indi-

vidualised, they have been shown to be more effective in improving symptomatology, functioning, and physical well-being in first episode psychosis [40] [41]. The importance of assessing the psychological wellbeing impact of lifestyle programmes has been emphasised [42].

In 2019 the UK Government stated that data generated by smart devices worn by individuals will enable the provision of intelligent personalised health interventions, and so people "will be co-creators of their own health" [43]. Actively incorporating and applying the functions of a Fitbit in an individual's daily routine can significantly increase physical activity, self-awareness, motivation, and goal setting, and reduce body weight [44] [45] [46]. Wrist worn activity trackers are a feasible and acceptable measure of physical activity for people living with psychosis [47].

Interventions to enhance motivation for engaging in physical activity can help elicit long-term healthy lifestyle behaviour change [48]. Motivational interviewing and goal setting are recommended tools in motivating those who may be unmotivated to engage in healthy lifestyle behaviours [49]. Healthy lifestyle intervention programmes should be grounded in behaviour change theory to foster self-efficacy and increase the likelihood of intervention efficacy [50]. To seek to address sleep, physical activity, and wellbeing of community-based depression and EIP service patients, a physical activity and sleep hygiene intervention (Well-Track) has been developed and tested over a period of four years. Based on our previous findings that Well-Track improved participants' physical activity, sleep quality, motivation, self-awareness, daily/weekly routines, wellbeing, healthy lifestyles, and quality of life, and reduced anxiety and depression levels [51] [52] [53] [54] [55], our hypothesis is that it will have a positive impact on depression, mental wellbeing, insomnia, and body weight in both EIP and ARMS patients.

The current development of the Well-Track intervention is an eight-week programme, and comprises the provision of a brief motivational interview and completion of a goal setting workbook, a free to keep Fitbit, sleep hygiene and physical activity information sheets and verbal advice, and two or three patient engagement, feedback and discussion sessions with a mental health worker. This present study investigates the impact of this intervention, it addresses the question: "What is the effect of Well-Track on depression, mental wellbeing, insomnia, and body weight for EIP and ARMS patients?"

2. Methods

2.1. Design

Open-label patient cohort design with no control group.

2.2. Participants

The sample was recruited from people using an EIP or ARMS service within the United Kingdom's (UK) National Health Service (NHS). Participants were included if they were aged 15 or over, had the mental capacity to consent, provided informed consent, and had the ability to understand verbal English. Exclusion cri-

teria was a medical reason meaning they could not wear a watch on their wrist, as it was an essential factor in Well-Track that participants wore a wrist worn Fitbit.

2.3. Setting

The intervention was implemented whilst participants were under the care of the ARMS or EIP services. ARMS work with young people and adults aged between 14 and 35 years old for up to one year to help prevent or delay the development of a first episode of psychosis. ARMS support people with all aspects of their lives including mental wellbeing, social functioning, employment and quality of life. Support provided includes: cognitive behavioural therapy (CBT), group therapy, family therapy, community-based support and telephone monitoring and support. In the EIP service every person is offered a National Institute for Health & Care Excellence (NICE) concordant package of care and treatment as per national standards [38]. Goals of the service relate to key performance indicators (KPIs) and include: reducing weight gain; improving wellbeing; reducing symptoms of psychosis and impact of those symptoms; improving physical activity; enabling better self-management; and enabling healthier lifestyles.

2.4. Intervention

An eight-week intervention which incorporated the provision of a brief motivational interview and completion of goal setting workbook with a mental health worker, a free to keep Fitbit (specific model: Fitbit Charge 4), sleep hygiene and physical activity information sheets and verbal advice, and either one or two follow-up patient engagement, feedback and discussion sessions with a mental health worker.

2.5. Procedure

The project was undertaken from June 2022 to June 2023. Approval for the study was gained from the NHS healthcare trust in which the services were based on 29 March 2022. (Reference number for approval: IFWT3). Patients were selected if they met inclusion/exclusion criteria and then they were provided with information about Well-Track and the evaluation. Informed consent was sought and required to begin Well-Track. Patients could withdraw consent or stop engagement with Well-Track at any point without the need to provide a reason. Following informed consent, at the data collection points participants completed the three self-report questionnaires and were asked to be weighed.

2.6. Measures

- Body weight in kilograms.
- Insomnia: Sleep Condition Indicator (SCI) is an eight item self-report measure of insomnia disorder and sleep quality; it is a valid, reliable and sensitive to change in insomnia severity [56].
- Depression: Patient Health Questionnaire-9 (PHQ-9) is a nine item self-report

measure of depression; it has good sensitivity and specificity for major depression as well as good internal consistency, validity and reliability [57].

- Wellbeing: Warwick-Edinburgh Mental Wellbeing Scale-14 (WEMWBS) is a 14 item self-report measure of psychological wellbeing; it has demonstrated strong validity and reliability [58].

2.7. Methodology and Analysis

Repeated measures ANOVAs were conducted to determine whether there were statistically significant differences in PHQ-9, WEMWBS, and SCI scores over the course of the 8-week intervention. Spearman's rho was used to calculate correlations. Data were analysed using the statistical software package SPSS Statistics 26.

3. Results

3.1. Well-Track as a Three-Point Engagement Intervention

Fourteen participants were males and ten were females. Mean age was 27.75 years (SD = 10.91), with an age range of 18 - 61 years (Table 1). Nineteen participants (79.2%) had symptoms of depression at baseline, and 15 (62.5%) by weeks 4 and 8. As defined by the PHQ-9, five participants (20.8%) had no symptoms of depression, 8 (33.3%) mild depression, seven (29.2%) moderate depression, three (12.5%) moderate to severe depression, and one patient scored above 20 points (severe depression). The baseline WEMWBS mean score at 44 was lower than the general population norms for England [58]. Based on SCI scores, 7 participants (29.2%) would meet a diagnosis of probable insomnia [56].

PHQ-9 remission is defined as a score of 5 or less, reliable improvement is a reduction of 6 points from baseline, and recovery is defined as both reliable improvement and remission being achieved. Table 2 shows the proportion of

Table 1. Characteristics of participants (n = 24) at baseline, 4 and 8 weeks.

Variable	Baseline		4 weeks		8 weeks	
	Mean (*SD*)	Range	*Mean* (*SD*)	Range	*Mean* (SD)	Range
Weight (kg)	82.80 (15.44)	56 - 112	83.16 (14.13)	56 - 106	80.15 (13.80)	55 - 96
PHQ-9	9.29 (5.89)	0 - 22	5.58 (3.68)	0 - 13	5.83 (4.40)	0 - 16
WEMWBS	44.04 (9.44)	25 - 65	48.54 (8.71)	32 - 70	48.67 (8.76)	35 - 66
SCI	20.92 (6.46)	11 - 32	22.88 (6.53)	8 - 32	21.42 (6.86)	8 - 32

Table 2. Intention-to-treat analysis of depression remission, reliable improvement, and recovery outcomes at 4 weeks and 8 weeks.

	4 weeks			8 weeks		
	Remission	Reliable improvement	Recovery	Remission	Reliable improvement	Recovery
PHQ-9	7 (25.9%)	9 (33.3%)	4 (14.8%)	4 (21.1%)	7 (36.8%)	3 (15.8%)

participants who had PHQ-9 defined depression at baseline who reached remission, reliable improvement, and recovery for PHQ-9 at 4 and 8 weeks.

Prior to statistical analysis, data screening was conducted to confirm that the dataset met the assumptions required of the general linear model. There were no outliers in the data, the Shapiro Wilk's test assessed all measures were normally distributed, and Mauchly's test of sphericity indicated that the assumption of sphericity had not been violated.

The reduction in PHQ-9 scores was statistically significant at the different time points during the intervention, $F(2, 46) = 11.98$, $p < 0.001$, a large effect size was observed partial $\eta^2 = 0.34$. Thus, 34% of the improvement in PHQ-9 scores was attributed to the intervention. Post hoc analysis with a Bonferroni adjustment revealed that there was a decrease in PHQ-9 scores from baseline ($M = 9.29$, $SD = 5.89$) to week 4 intervention ($M = 5.58$, $SD = 3.68$), a statistically significant mean decrease of 3.71 95% CI [1.16, 6.25], $p = 0.003$; and from baseline to week 8 ($M = 5.83$, $SD = 4.40$), a statistically significant mean decrease of 3.46 95% CI [1.49, 5.42], $p < 0.001$. The PHQ-9 scores indicated depression improvement was maintained to week 8, but the very slight mean decrease of -0.25, 95% CI [-2.25, 1.75], $p = 1.000$, from week 4 to week 8, was not statistically significant.

WEMWBS data Mauchly's test of sphericity indicated that the assumption of sphericity had not been violated, $\chi^2 (2) = 0.90$, $p = 0.33$. The increase of the WEMWBS scores was statistically significant at both points during the intervention, $F(2, 46) = 5.938$, $p = 0.008$, partial $\eta^2 = 0.19$. The large effect size confers 19% of the improvement in WEMWBS was accounted for by the intervention. Post-hoc analysis with Bonferroni adjustment revealed that there was an increase in the WEMWBS scores from baseline ($M = 44.04$, $SD = 9.44$) to week 4 ($M = 48.54$, $SD = 8.71$), a statistically significant mean increase of 4.50 95% CI [-8.94, -0.06], $p = 0.046$. Similarly, an increase in the WEMWBS scores was observed between baseline and week 8 ($M = 48.67$, $SD = 8.76$), a statistically significant increase of 4.62 95% CI [-8.07, -1.18], $p = 0.006$. Wellbeing improvement was maintained to week 8.

For SCI data, the assumptions for repeated measures ANOVA were met and Mauchly's test of sphericity indicated that the assumption of sphericity had not been violated, $\chi^2 (2) = 0.90$, $p = 0.333$. An overall change in sleep index score was not statistically significant following the intervention, $F(2, 46) = 2.64$, $p = 0.082$, partial $\eta^2 = 0.103$. However, a post hoc analysis with a Bonferroni adjustment revealed there was an improvement from baseline ($M = 20.92$, $SD = 6.46$) to week 4 ($M = 22.88$, $SD = 6.53$), a statistically significant mean improvement of -1.96 95% CI [-3.86, -0.05], $p = 0.043$. The average sleep index decreased slightly by week 8 ($M = 21.42$, $SD = 6.86$) but still remained above baseline.

Weight did not change significantly from baseline ($M = 78.18$, $SD = 14.80$) to week 4 ($M = 78.83$, $SD = 14.65$) and week 8 ($M = 78.20$, $SD = 15.19$). Weight was not related to any of the measures at any time point. Pearson's correlation indicated a statistically significant correlation between PHQ-9 and WEMWBS ($r =$

−0.70, *p* < 0.001), PHQ-9 and SCI (*r* = −0.56, *p* < 0.001), and between WEMWBS and SCI (*r* = 0.52, *p* < 0.001) at baseline.

3.2. Well-Track as a Two-Point Engagement Intervention

Analysis was undertaken on all those who completed Well-Track as a two-point engagement intervention, *n* = 34 (18 males and 16 females), this represents those who did not attend a third engagement session. Mean age was 28.74 years (*SD* = 10.60), with an age range of 18 - 61 years (Table 3).

Twenty-seven participants (79.4%) had symptoms of depression at baseline, and 20 (58.8%) by week 4. As defined by the PHQ-9 [57], 7 participants (20.6%) had no symptoms of depression at baseline, 11 (32.4%) had mild depression, 8 (23.5%) moderate depression, 5 (14.7%) moderate to severe, and three participants (8.8%) scored above 20 points (severe depression). The WEMWBS mean score was lower than the general population norms for England (*M* = 51.0, *SD* = 7.0) [58]. Based on SCI scores, 12 participants (35.3%) would meet a diagnosis of probable insomnia [56].

The reduction in PHQ-9 scores was statistically significant from baseline (*M* = 9.91, *SD* = 6.55) to after 4 weeks of the intervention (*M* = 6.29, *SD* = 4.61), *t* (33) = 3.71, *p* < 0.001, a moderate effect size was observed (Cohen's *d* = 0.64). The increase of the WEMWBS scores was statistically significant from baseline (*M* = 44.44, *SD* = 10.53) to week four (*M* = 49.47, SD = 9.42), *t* (33) = −3.13, *p* = 0.002, a moderate effect size (Cohen's *d* = −0.54). There was a significant improvement in symptoms of insomnia from baseline (*M* = 19.88, *SD* = 7.48) to week 4 (*M* = 22.41, *SD* = 6.69), *t* (33) = −2.57, p = 0.007, Cohen's *d* = −0.44. The weight did not change significantly from baseline (*M* = 81.91, *SD* = 15.40) to week 4 (*M* = 82.28, *SD* = 15.94), *t* (16) = −0.42, *p* = 0.339.

4. Discussion

This study investigated the impact of Well-Track on depression, mental wellbeing, insomnia, and body weight. The study team found that EIP and ARMS patients will choose to undertake Well-Track, providing evidence of the acceptability of the intervention. The findings showed that EIP and ARMS patients could benefit from Well-Track in terms of reducing symptoms of depression and insomnia, and improving mental wellbeing. Change in body weight is a complex

Table 3. Characteristics of participants (*n* = 34) at baseline and after 4 weeks of intervention.

Variable	Baseline		4 weeks	
	Mean (*SD*)	Range	Mean (*SD*)	Range
Weight (kg)	82.73 (14.45)	56 - 112	82.60 (15.52)	56 - 108
PHQ-9	9.91 (6.55)	0 - 25	6.29 (4.61)	0 - 20
WEMWBS	44.44 (10.53)	25 - 65	49.47 (9.42)	32 - 70
SCI	19.88 (7.48)	5 - 32	22.41 (6.69)	8 - 32

issue and caused by many factors, and while significant findings were not observed, a drop in body weight was seen at the eight week point, and reductions in weight may be a positive outcome for some people with psychosis.

Well-Track has the potential to address depressive symptoms of people at-risk of SMI and who are experiencing psychosis. Psychotherapy can be effective in treating depression but is costly and requires time commitment, with non-response rates of 60% [59] [60]. Antidepressants can reduce depressive symptoms for some people; however, not all respond, and adverse effects can include weight gain, increased risk of falls, gastrointestinal and sexual difficulties, insomnia, and severe headaches [61] [62] [63]. Many people at risk of SMI or with SMI will have tried psychotherapy and multiple antidepressants, and may still be experiencing depression (possibly meeting a diagnosis of treatment resistant depression [TRD]), and so alternative interventions with antidepressive effects could be a good option. An advantage of Well-Track is that it could also be offered whilst people are undertaking psychotherapy or taking antidepressant medication.

Participant improvements on the WEMWBS measure indicate a positive impact of Well-Track on an individual's wellbeing, subjective happiness, life satisfaction, self-realisation, and psychological functioning. These are all factors which are important for quality of life, coping, and thriving. Whilst there are no directly comparable interventions, the improvement in wellbeing through Well-Track was greater than an intervention providing access to community-based physical activities for participants who were mental health service users [64], perhaps highlighting the added value of an individualised approach using a motivational interview, goal setting, and feedback. The findings indicate that this study's approach (providing goal setting, progress monitoring, structure, and support to assist people in physical health and lifestyle management to encourage healthy lifestyles and increase health literacy) supports the evidence of the value of this approach [42].

Evidence indicates that sleep disturbance plays an important role in the pathogenesis of schizophrenia [19], which highlights the potential utility of targeting sleep difficulties with Well-Track in EIP and ARMS services. This can potentially aid early prevention in at-risk and early psychosis populations. NICE recommendations for the treatment of short-term insomnia are non- pharmacological interventions, e.g., insomnia cognitive behavioural therapy (iCBT), as the first method and, where this fails, a follow up with a brief course of a non-benzodiazepine hypnotic prescription [65]. Further investigation could consider if Well-Track may be a useful and potentially more acceptable and lower-cost intervention for insomnia than either iCBT or non-benzodiazepine hypnotic prescription.

No significant rise in body weight and maintaining body weight can viewed as a positive in at-risk and early psychosis populations [29], as body weight is a complex issue associated with, for example, social and psychological factors, medication that can increase body weight (antipsychotics, antidepressants) and

the fact that muscle is heavier than fat, so exercise does not necessarily lead to weight loss. An average loss of 2.65 kg from baseline to 8 weeks is a potentially meaningful loss of weight in the real lives of participants who may have put on weight over the period of their mental health difficulties and psychosis experiences and treatment; this is important as there is an association of weight gain with the cause of distress, reduced self-worth, poor sleep quality, and engaging in less physical activity or exercise [31] [32]. A 12-week, two 45-minute supervised weekly exercise and health behaviour intervention as part of an EIP routine service within the UK saw no significant change in body weight (a rise of 0.7 kg) [50]. Well-Track may be a more effective and less resource intensive way of supporting maintaining body weight in this population.

5. Limitations

Study limitations include the lack of control group and relatively small sample size. A confounding factor is that the participants would have been receiving support and treatment from the EIP and ARMS services during the Well-Track intervention. People who agreed to participate were self-selected; thus, it is possible more participants with better than average mental health (e.g., experiencing fewer psychotic symptoms) agreed to participate. The participants all attended an EIP or ARMS service in the UK reducing generalisability.

6. Conclusions

Well-Track has a positive impact on insomnia, wellbeing, and depression either as a two or three engagement point intervention. Benefits are seen at 4 weeks, and sustained at 8 weeks indicating longer term benefits. The addition of a third engagement point at 8 weeks may help maintain benefits and support longer term application of tools, knowledge and positive healthy lifestyle behaviour change in people's lives. An appropriately powered multi-site randomised controlled trial with longer term follow-up to investigate efficacy of Well-Track could provide further evidence.

There is a lack of effective physical activity interventions available in EIP services [39], and Well-Track has been found to be an effective option, that could potentially bridge this gap. Well-Track has demonstrated that mental health services can successfully address health and wellbeing associated lifestyle factors that are important to their patients. Improved mental and physical health and wellbeing are key aims of EIP and ARMS services. These results show that EIP and ARMS service users can benefit from this relatively simple and low-cost intervention that meets requirements of service delivery goals and key performance indicators (KPIs). A manualised version of Well-Track is now available to access free of charge via: https://www.nhft.nhs.uk/research/.

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Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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