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Reducing sedentary behaviour and cognitive function in community-dwelling older people: Study protocol for a randomized feasibility study

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ABSTRACT

(1) Background: Sedentary behaviour is high amongst older adults and increases with ill-health and cognitive impairment. Although there is strong evidence of the deleterious effects of high sedentary levels on cardiovascular health, its role and risk to cognitive health is inconclusive. In light of the recent lockdown and COVID-pandemic, the use of web-based health promotion amongst older adults has become more pertinent to attaining healthier living. Therefore, this study proposes to test the feasibility of an online health coaching intervention in people aged 50+ with mild cognitive impairment (MCI). (2) Methods: This is a 13-week unblinded, single-centre randomized feasibility study. People with MCI who meet study criteria (50+ years and MCI diagnosis) will be recruited from community settings nationwide. Participants will be randomized to receive online coaching or health information. The study reporting will follow the CONSORT statement. Primary outcomes will be feasibility of study and acceptability of online coaching intervention. (3) Discussion: It is hoped that if the intervention is feasible and acceptable, the study will progress to a definite large-scale study to evaluate clinical and cost-effectiveness.

1. Introduction

Sedentary behaviour refers to any waking behaviour characterised by energy expenditure of ≤ 1.5 METs in reclining, lying and sitting postures [34]. Levels of sedentary behaviour is high amongst the older adults and increases with age co-morbidities and cognitive decline [12]. 60% of older adults world-wide reported sitting for more than four hours per day and when device-measured, 67% of the older population were sedentary for more than 8 in their waking day [15]. There is evidence of deleterious health impacts of sedentary behaviors, with possible independent associations with all-cause mortality, cardiovascular disease mortality, cardiovascular disease incidence, cancer mortality, and type 2 diabetes incidence [3]. Although observational studies have demonstrated some associations between sedentary behaviors and cognitive health, evidence on causal relationship is lacking (Olawale [26]).

People living with MCI are not only at risk of further cognitive decline and dementia, [21] [19], but also likely to engage in less physical activity and increased sedentary behaviours [35]. A recent observational study found that being sedentary for $>=8$ h/day was associated with

1.56 (95%CI=1.27–1.91) times higher odds for MCI [35]. A separate cross-sectional study indicated that people with probable MCI were less active and engaged in more sedentary behaviour, compared with people without MCI [9]. However, the study did not find associations between cognitive scores and the levels of sedentary behaviour in people with MCI, likely due to their MCI status not diagnosed by a doctor.

A review of strategies to reduce sedentary behaviour amongst adults found that the most promising interventions used behavioural change techniques such as self-monitoring and problem solving [11] [4]. A separate systematic review of interventions to reduce sedentary behaviour in non-working older adults found that interventions which incorporated goal setting, individualized feedback, motivational sessions reduced objectively measured sitting time by 3.2%–5.3% of waking time or up to 54 min per day [1]. The use of the internet and web-based mobile devices for health promotion are increasing amongst older adults. This trend is likely to continue due to increase in general internet use amongst adults aged 65+ years, particularly as the nation emerge from the height of COVID-19 pandemic lockdown [22]. Also, web-based health promotion is cheaper to deliver and may overcome usual barriers to participation in healthy behaviours such as

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time commitment and inability to access facilities [36]. In relation to their effectiveness, a meta-analysis of digital behaviour change interventions (DBCI) in older adults indicated that using platforms such as mobile applications, websites, wearable devices reduced sedentary time by 58 min per day (SMD = -0.45; 95%CI -0.69, -0.19; $p < 0.001$) [33].

Promoting the use of digital health intervention in the older people has challenges. A significant proportion of older adults in the UK are digitally excluded and never used the internet. The Office of National Statistics estimated that 2.2 million adults aged 65+ years in the UK have not used the internet in the past 3 months and 72% of all digitally excluded is amongst those aged 65 years and older [23]. Although this may have improved in recent times and perhaps necessitated as a result of the COVID pandemic, this cohort of older adults are hampered by challenges, which may not have improved over time such as low income, live alone, mobility difficulty, skills and memory problems [13]. Implementing a simple and effective approach to behavioural change is also important. Previous research indicated that complex interventions with multiple behavioural change techniques (BCT) linked to multiple theories and models could reduce the uptake and effectiveness of such interventions [14]. The use of most effective BCTs in older people linked to a single specific relevant theory may be a better approach [14]. For instance, French et al. [10] confirmed in a systematic review that many self-regulation interventions used in younger people may not be appropriate in older adults and suggested that BCTs such as barrier identification/problem solving and providing rewards contingent on successful behaviour were more effective in improving physical activity uptake in older people [10].

In light of the aforementioned evidence, we propose to test the feasibility of an established intervention-The WALC intervention (Walk; Address sensations; Learn; Cue) in older adults at risk of cognitive decline with a view to test for effectiveness on cognitive function in a later study. The WALC intervention was originally designed to motivate community-dwelling older adults to increase physical activity and is based on Social Cognitive theory [29]. The WALC intervention combines goal-setting and self-monitoring of behaviour change techniques using a digital platform (pedometer and online coaching). Our approach to delivery would mitigate some of the challenges posed with implementing the WALC-R (R=remote) intervention in older people. First, we have adapted the original WALC intervention so that it can be delivered remotely in real-time, via supported coaching using the internet videoconferencing. This means that a coach will deliver same session remotely as they would have done in a face-to-face setting. Secondly, the WALC-R intervention is simple, based on a single behavioural theory (Social Cognitive theory) and uses few BCTs proven to be effective in the older population. Further, the researcher will prompt participants at regular intervals using telephone, text messages and email about ongoing activities such as wearing and removal of activity tracker, visits/sessions. Computer / Information technology skills required to participate in the study is basic, such as to check/send emails. The researcher will also be available for questions and to assist with study-specific I.T. issues such as how to connect to the video-conferencing interface.

1.1. Aim

This primary aim of the study is to establish the acceptability of the proposed online health coaching intervention in community dwelling older people living with mild cognitive impairment. In addition, the study will determine how many participants can be recruited, the rate of adverse event and cost of delivery. The secondary aims are to estimate the difference between treatment and control groups at baseline and follow-up of (1) device- measured sedentary behaviour (2) self-reported sedentary behaviour (3) verbal fluency (4) pre-morbid intelligence (5) self-rated health.

1.2. Prior work

This feasibility study forms part of a three-phase project, which employs the Behavioural Epidemiological Framework to improve evidence around the role of sedentary behaviour in cognitive health [32]. Following a scoping literature review, a systematic review was conducted to explore evidence in this area. The systematic review found inconclusive evidence on the overall direction of associations between sedentary behaviour and cognitive function in older people, with limitations such as the quality of studies available and the use of self-reported sedentary behaviour as outcome (Olawale [25]). This was followed by a secondary analysis of data from The Longitudinal Study of Ageing in Ireland, which demonstrated cross-sectional and longitudinal associations between sedentary behaviour and poorer cognition in middle-age and older adults [25]. However, intervention studies are now required to confirm effects of reducing sedentary behaviour on cognition.

2. Materials and methods

2.1. Design

This will be a 13-week unblinded, single-centre randomized feasibility study. The intervention is comprised of an initial group education session, fortnightly coaching sessions and the provision of a pedometer and diary to enable participants monitor their daily physical activity. Participants in the control group will receive information leaflets which outlines the benefit of being physically active. The design will adhere to the Consolidated Standards of Reporting Trials statement for feasibility trials (CONSORT) [8]. Ethical and research governance approval was sought and granted from London city and East Research Ethics Committee (IRAS 280073), the Health Research Authority and Research and Development departments in both Anglia Ruskin University and CPFT. This study is registered on ClinicalTrials.gov (NCT04464538). A flow diagram of the study is shown in Fig. 1, and the schedule of enrolment, interventions and assessments is provided in Fig. 2.

2.2. Setting and participants

The study will be conducted remotely in the community settings and potential participants will be sought from the community services including mental health teams and memory services nation-wide. The following eligibility criteria will be used:

- Community dwelling adults aged 50+ years
- Doctor diagnosis of Mild Cognitive Impairment OR MCI diagnosis which meets Petersen Criteria [28]
- Participants must have a working knowledge of English
- Participants must be able to provide informed consent

Participants will be excluded if (a) diagnosed by a doctor with dementia (b) diagnosed with severe mental health conditions and substance use disorders (c) diagnosed with other neurological conditions. We aim to recruit 40 participants and a final target sample of 24 (12 per group) after factoring a 40% attrition. This total sample size is within the range for feasibility study. [17] [18].

2.3. Recruitment and screening

A member of the clinical team will screen potential participants for initial eligibility (from medical notes, clinic records and/or clinical consultations) and, if appropriate, given information about the trial. The clinician will then arrange an appointment to discuss the trial, along with the opportunity to ask any questions. We will give people 24 h to decide if they would like to participate. If they are happy with the information they receive, they will be contacted by a member of the research team to give informed consent. This study proposes to recruit patients with mild cognitive impairment. Therefore, a mental capacity

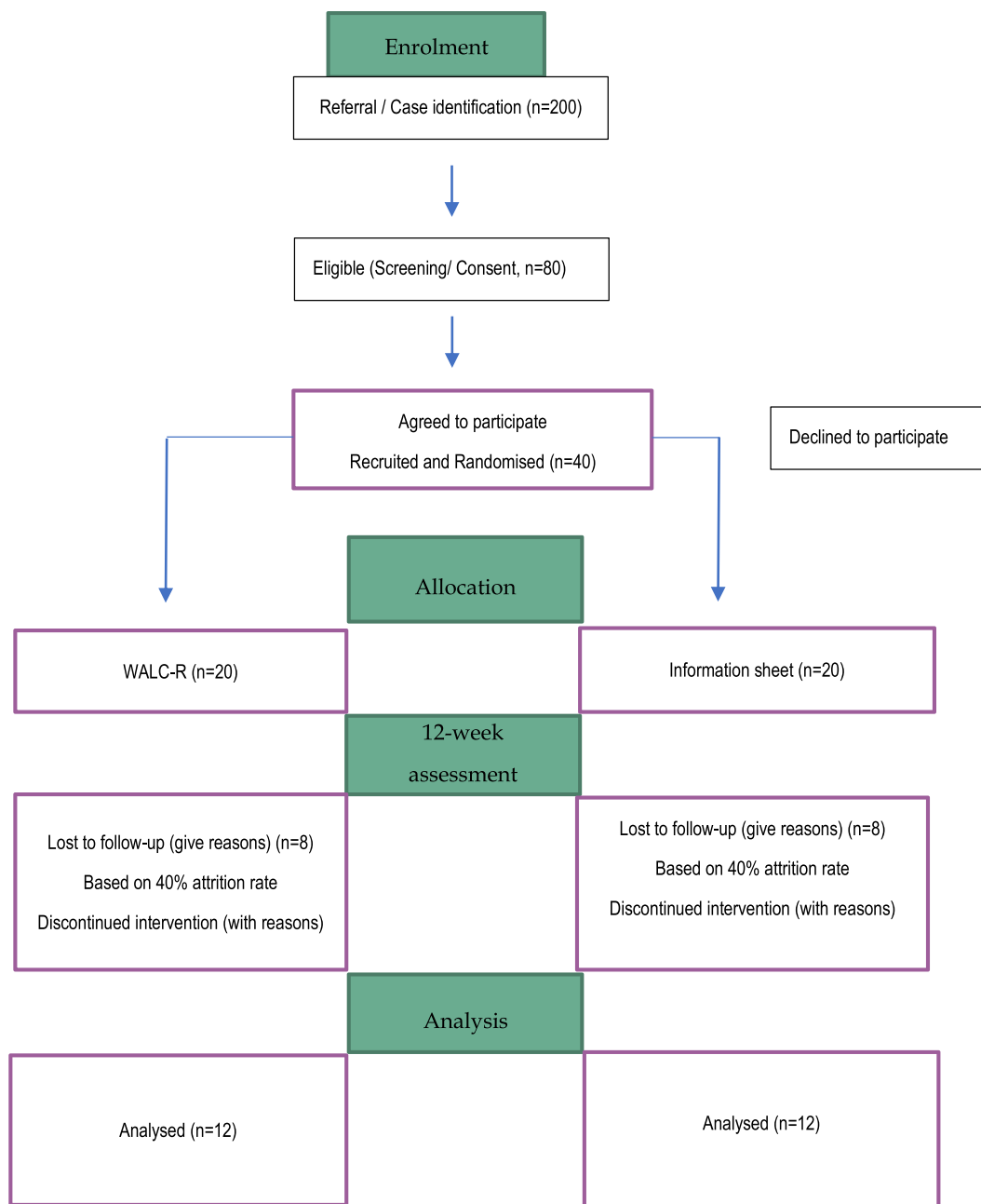


Fig. 1. Study flow diagram.

test will be conducted during the process of consent to ensure that participants understand, retain and weigh up the information available to make a decision about consenting. Participants’ general practitioners will be informed about their enrolment onto the study. Once enrolled, participants will be asked to wear an accelerometer for 7 days at baseline and follow-up. Each participant will be reimbursed £10 for wearing the accelerometer at each time-point. After completion of the baseline measures, the participants will be informed of their allocation status.

2.4. Randomization, post-randomization withdrawals and exclusions

This study proposes a simple randomization of participants into intervention and control arms. Randomization process will be overseen by the researcher using freely available software from Sealed Envelope: <https://www.sealedenvelope.com/help/simple-randomiser/students/>. Participants will be randomly allocated to re-

ceive either ‘WALC-R’ (intervention group) or information on recommended physical activity for older adults (control group). Approximately 5 participants will be randomized each month over 8 months. Subjects may discontinue participation in the trial intervention and/or the trial at any time. Unless a subject explicitly withdraws their consent, they will be followed-up wherever possible and data collected as per the protocol until the end of the trial. Documentation will be completed on withdrawal to confirm the date and reason for withdrawal.

2.5. Summary of interventions

The WALC-R (Walk, Address sensation, Learn exercise, Cue-Remote) intervention is not a walking/physical activity group, rather, a forum where the concept of sedentary behaviour and strategies to reduce these behaviours are coached. The WALC intervention has been validated in several studies for use in the older population and people living with

Time point	Enrolment	Allocation	Baseline	Follow-up (week 13)
Eligibility screen	√			
Informed Consent	√	√	√	√
Baseline measures (listed below under assessments)	√			
Allocation		√		
INTERVENTIONS				
Treatment group			↔	
Control group			↔	
ASSESSMENTS				
Demographic			√	
Sedentary behaviour/day (ActivPAL)			√	√
Self-reported sedentary behaviour (SBQ)			√	√
Verbal Fluency (COWAT)			√	√
Self-rated health (EQ-5D)			√	√
Adverse event reporting				√
Interview				√

Fig. 2. Schedule of enrolment, intervention and assessments. SBQ (Sedentary Behaviour Questionnaire); COWAT (Controlled Oral Word Association Test), EQ-5D (Euroqol 5-dimension questionnaire).

schizophrenia and more recently with serious mental illness [2, 30, 37]. This study proposes to adopt the WALC intervention, which incorporates elements of the COM-B behavioural change model to address capability, opportunity, and motivational barriers to reduce sedentary behaviour [20]. Unlike original and previous versions of the WALC intervention,

individualized coaching sessions will be delivered remotely, hence the ‘R’ in WALC-R. The principle is same as in the original WALC, but unlike a face to face-delivered coaching session, sessions will be held in real time using a video-conferencing interface such as Zoom, Skype, and Microsoft TEAMS. The level of computer skills required by the partici-

participants will be able to check and write an email. Following initial discussions with a researcher/coach via telephone, a link to the video calls for baseline/follow-up and coaching sessions will be attached to emails sent to participants. Participants will only need to click the link to access the relevant sessions. Participants with difficulty in accessing video chat applications will be able to speak with a researcher, who will be able to guide them over the telephone. The WALC-R will consist of a group initial education session, fortnightly health coaching sessions, and self-monitoring of daily activity levels using pedometer and diary.

2.5.1. Initial group education session (online)

Participants assigned to the WALC-R intervention will attend a virtual baseline educational group session which will include a maximum of five people. The aim of the sessions will be to introduce the basics of the benefits of walking for exercise and why exercise is beneficial, as well as to give information, support and motivation to help participants to independently walk more in their daily routines. In the group sessions, we will also introduce the concept of sedentary behaviour and the harms and strategies to sit less and move more, including disrupting prolonged periods of sitting. At the educational session, researchers will have information on the participants' habitual levels of physical activity obtained from baseline data collection. The group session will also include goal setting, in which participants will be encouraged to set their own daily walking targets to increase their habitual levels of walking. All participants will be given a pedometer to self-monitor how far they walk and a diary to record activity context throughout the intervention daily.

2.5.2. Continuing support and coaching (online)

Participants will meet briefly (20–30 min) via the internet video-conferencing, with an assigned coach every 2 weeks. The participant and coach will review the participant's walking calendar and address any barriers to and facilitators of engaging in physical activity and reducing sedentary behaviour. Participants will receive a pedometer (Fit-bit watch) in adjunct with coaching sessions. In addition to instruction manual and paper diary sent out with the pedometer, a researcher will be available to discuss and assist with any issues encountered with its operation.

2.6. Control group

Participants in the control group will complete baseline measures, and then they will receive written information on the benefits of increasing activity levels. This advice will be given in accordance with NHS guide on physical health.

2.7. Follow-up assessment

The follow-up assessment will be undertaken at the end of the intervention after 13 weeks. At follow-up, all measures will be repeated (apart from sociodemographic information). Each participant will again receive a £10 voucher for wearing an accelerometer.

2.8. Data collection

2.8.1. Primary outcome: acceptability and feasibility

The primary outcomes of this study are the acceptability and feasibility of intervention for delivery in the community settings and for a full-scale RCT. Acceptability will be qualitatively assessed at the end of week 13 via semi-structured interviews with study participants. Feasibility will be tested by measuring (1) whether it was possible to recruit sufficient participants into the study within a particular time frame and (2) how many people who were recruited into the study completed the intervention (3) cost of delivering the intervention and (4) how many people who received intervention sustained adverse events.

2.8.2. Secondary outcomes

Sedentary behaviour and physical activity time per day will be recorded using ActivPAL inclinometer. ActivPAL devices, waterproofing material and adhesive dressings will be mailed to participants using paid self-return postage. All participants will be required to wear the ActivPAL continuously for at least 7 days at baseline that will measure habitual sedentary behaviour and walking activity each day [7]. The inclinometer will record how many minutes per day each participant is sedentary and engages in light, moderate and vigorous physical activities. A recording is made of each 60-second period (called an 'epoch'), and this is classified as being sedentary or light, moderate or vigorous physical activity. The cut-off points are defined according to metabolic equivalents (METs) of sedentary (<1.5 METs), light (1.5–3.99 METs), moderate (4.00–6.99 METs) and vigorous (>7+ METs). We will collect data on the total minutes of sedentary behaviour per day, number of disruptions in sedentary behaviour and total time spent in physical activity (minutes per day in light, moderate and vigorous activity). We will measure if the WALC-R intervention group changes pre- and post-intervention in sedentary behaviour and physical activity and also measure if this differs from the control group. In addition, the following will be measured at baseline and follow-up:

- 1 Self-report sedentary behaviour: The Sedentary Behaviour Questionnaire (SBQ) [31] will be used to capture self-reported sedentary behaviour. Participants will respond to the question 'on a typical weekend day/ weekday, how much time do you spend doing the following?'. Nine activities are listed including television viewing, playing video games and sitting reading a book. Response are grouped into the categories: 'None', <=15 mins, 30, 1 h, 2 h, 3 h, 4 h, 5 h, 6+ hours.
- 2 Verbal fluency: Participants' verbal ability will be tested using the Controlled and Oral Word Association Test: COWAT [27]. Participants will be required to make verbal associations to different letters of the alphabet by saying all the words, which they can think of beginning with a given letter. Participants are scored based on how many words they can provide in 60 s.
- 3 Pre-morbid Intelligence: This will be tested using the National Adult Reading Test [6]. Participants will be asked to read a list of 50 words, and they will be scored based on whether or not they pronounce each word correctly.
- 4 Health Related Quality of Life: The participants will self-rate their health using the EQ-5D-5 L. Five dimensions are provided (mobility, self-care, usual activities, pain/discomfort and anxiety/depression) and five response levels: no problems, slight, moderate, severe, unable to/extreme problems. [16] In addition, the EQ- Visual Analogue Scale (VAS) records the respondent's overall current health (0–100). Higher VAS scores represent best perceived health and vice versa.

2.8.3. Cost of delivering intervention

All costs associated with the intervention and delivery of intervention (e.g., research time, travel cost, equipment, I.T. support and training) will be estimated. However, we plan to evaluate the cost-effectiveness of proposed intervention in the full trial. The EQ-5D-5 L will be used to measure the Health-Related Quality of Life (HR-QoL) status in the participants pre- and post-treatment.

2.8.4. Data analysis-quantitative

We will summarise all data by treatment group. Statistical measures of central tendency and dispersion such as mean, standard deviation (continuous variables), frequency distribution, interquartile range (IQR) and median (categorical variables) will be used in descriptive statistics. Characteristics of follow-up and lost-to-follow-up participants will be compared. Non-parametric statistical methods will be used for bivariate analysis. Stata version 16 software will be used to perform the analysis. Accelerometer data will be processed using activPAL3 software (version 7.2.28)

2.8.5. Data analysis-qualitative

A topic guide will be created with open-ended interviews and this topic guide will be submitted for ethical approval. With the consent of participants, semi-interviews will be conducted. We anticipate that each interview will take approximately 30–45 min. Interviews will be digitally recorded, and transcripts will be anonymized for identifiable information. Conceptual content analysis will be utilized. Themes related to the (non)acceptability of our intervention will be extracted and coded. We will adopt a flexible approach to identifying and coding for concepts as they arise during the process. Finally, the frequency of the concepts identified will be analysed using QSR Nvivo software.

2.8.6. How will results be used?

At the feasibility stage, the research will evaluate the acceptability of proposed health intervention to participants (2020–2022). Results from the present feasibility study will be presented at national conferences in order to stimulate enthusiasm for centres to participate in the intended future trial, where the effectiveness of the intervention will be tested (2022–2025). If found effective, the results will be disseminated to relevant stakeholders in advocacy, academia, research, health and social care professional groups (Chartered Society of Physiotherapists) and patient groups (Alzheimer's society). The researcher hopes that dissemination of findings would create opportunities for collaboration with the stakeholders to inform local and national guidelines on the use of non-exercise, sedentary reducing interventions in older adults with early-stage dementia. It is hoped that these guidelines will inform clinical / health practices within primary and secondary care.

2.8.7. Other ethical consideration

The researcher is GCP trained. Participants will be reminded that their involvement in the study is voluntary and they have the right to withdraw from the study at any time. Although unlikely, cognitive difficulty in people with mild cognitive impairment might impact consent capacity. Also, the rate of cognitive decline in people with MCI is hard to predict. As in routine dementia trials, patients who lack capacity to consent can agree to participate and, in compliance with the Mental Capacity Act (2005), advice will be obtained from a personal consultee. For those relatively few participants unable to give informed consent, and for whom no personal consultee is available, an attempt will be made to find a nominated consultee. The most common route for a nominated consultee might be an independent mental capacity advocate (IMCA). Experience in other trials suggests IMCAs are rarely willing to consider this role. If this is the case, an alternative professional (e.g., GP) who is entirely independent of the trial may be approached. If one attempt to find a nominated consultee is unsuccessful, we will not attempt further to recruit the participant.

It is possible that during individual coaching sessions, participants may raise issues that are sensitive or are a source of anxiety or concern about their activity, condition or health care. If this happens, the coaches are trained to respond to the situation, which might involve taking a break, stopping the session or referring to your GP. All adverse events will be documented, while severe events and adverse reactions will be documented and reported to the steering committee and REC. Documentation and records will be maintained and regularly updated on the trial master file and case report forms. Participants will be rewarded with £10 vouchers for wearing their activity monitors continuously for 7 days at baseline and follow-up. Data collected from patients will be secured and kept safe. In order to achieve this, measures such as securing documents and hardware in safe storage, encoding information, encrypting data will be taken. Informed consent will be sourced and received from participants before including them in the study. Their GPs will be informed of their participation once included in the study. Participants will be assured of confidentiality / anonymity and safety of information and data received. They will be assured that any information divulged (opinions, experiences and perception) will in no way affect their health entitlements and access to health services. Finally,

study results will be disseminated to all participants at the end of the project.

2.8.8. Patient and public involvement

This study proposes to set up an advisory group with support from the Service User and Carer Involvement team in CPFT to inform the design of participants' information sheet, and consent forms. PPI will also help with recruitment and retention strategies. In addition, PPI will be involved in the dissemination throughout the study using social media, conference and co-writing reports / peer-reviewed publication.

3. Discussion

This study aims to test the feasibility and acceptability of online coaching as an intervention to reduce sedentary activity in older people living with mild cognitive impairment. If successful, a larger trial will be conducted to ascertain whether or not the WALC-R intervention compared with providing information about physical activity could improve the cognitive function in older adults with Mild Cognitive Impairment. The use of digital behavioural change intervention (DBCI) has become pertinent, given the COVID pandemic and distancing rules society is facing. However, digital health interventions are not without challenges such as inequality of access and complexity of delivery. Our intervention addresses some of these challenges by delivering a simple, tried and tested intervention (WALC) using personalized coaching via internet video chat. Although we cannot totally ameliorate the issue of digital exclusion, participants who have access to digital device and internet will only require basic skills such as checking and writing an email to be able to participate. Support will be available for participants interested but have difficulty with the minimum required computer skills. Finally, studies on the potentially modifiable risk factors for cognitive decline are important given the challenge presented by the rise in dementia prevalence in most regions of the globe [5]. Behavioural risk reduction has an important role to play in dementia prevention research and public health agenda (O. [24]).

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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