Mental Health and Productivity Pilot

WP7 Protocol

Piloting an employer and employee return to work toolkit to improve mental wellbeing and enhance the successful transition back to work following long term sick leave

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1. Background and rational

Mental health issues increasingly account for a significant proportion of long-term sickness absence from work (Hampson & Jacob, 2020) and those who are absent for six months or longer have less than a 50% chance of ever returning to employment (Waddell, Burton 2006). Therefore, early intervention to support an employee back to work is vital for the employee (e.g. financial, social, psychological gains) and the employer (e.g. reduced turnover, recruitment costs, retention of knowledge, and culture of wellbeing).

1.1. Sickness absence

Sickness absence associated with poor mental health costs UK employers £7 billion each year, (Hampson & Jacob, 2020). However, the cost is not at an economic level only, as there are also major social, psychological and financial implications for individuals on sick leave and for those unable to return to work (Nielsen et al, 2018). Long-term sick leave is a strong predictor of disability pension, higher risk of unemployment and job termination (Hultin et al., 2012). Other negative outcomes of sickness absence are inactivity, isolation, reduced workability and productivity (Gustafsson & Marklund, 2011; McTernan et al. 2013; Woo et al. 2011, Tsuchiya et al. 2012), and reduced wellbeing and impaired self-image leading to the individual potentially withdrawing from society and support networks (Gustafsson & Marklund, 2011).

A recent survey with 1,899 employers across the Midlands (Stanfield et al., 2020) suggests the main contributors to poor mental health include lone or remote working, client expectations (time, quality and cost), job insecurity and recruitment practices. Yet, employers cite non work-related issues as the major cause of mental ill-health.

Although the trend of sickness absence has generally been falling since 2009, mental-health related sickness absence is on the rise (12.4% in 2018 vs 9.1% in 2009), and it is likely that there is an under-estimation of mental-health related sick leave by employees masking their true reasons for sick leave (ONS, 2019).

1.2. Mental health and return to work support

A systematic review and meta-analysis by Nigatu et al. (2016) found that return to work interventions for individuals with a common health problem were effective in reducing the number of sick-leave days if the interventions focused on providing cognitive behavioural therapy or a problem-solving approach for addressing specific barriers to return to work. These interventions included regular contact and communication with the individual's workplace. Compared to the control group, these types of interventions

reduced the number of sick days by a mean difference of −13.38 days (95% CI −24.07 to −2.69). A more recent Systematic review and meta-analysis led by Mikkelsen (2018) also found return to work interventions to have a significant positive impact at reducing the duration of sick leave, with an average reduction in time until return to work by 15-30 days; supporting the economic value of investing in return to work interventions. However, they only found strong evidence for communication and contact with the workplace for an effective return to work (Mikkelsen et al., 2018). Whilst good communication and contact with the workplace are key contributors for an effective return to work, very few RTW interventions have been implemented in the UK. To date, one evidence-based intervention implemented in the UK, is the Individual Placement and Support (IPS) programme. The programme is highly effective at getting people who experience severe mental health conditions back into work. However, the programme does not support employees with poor mental health wellbeing on long term sick leave. Whilst Government, charity and in-house led return to work initiatives for employees with common mental health conditions are also available, the effectiveness of these is yet to be tested.

Traditional RTW programmes in the UK also lack a person-centred approach and are resource consuming (not designed to be self-guided), limiting the implementation in smaller organizations. Although evidence suggests that good communication is a predictor of early RTW, most RTW programmes have not utilised mirror conversation techniques, thus preventing transparency and open conversations between employers and employees. Furthermore, RTW programmes implemented to-date have not provided opportunities for training and upskilling employers, which may have hindered the effective implementation and sustainability of such programmes (Mikkelsen et al., 2018). Additionally, most RTW interventions lack an integrated approach to worker health, safety and wellbeing where there is a strong organisational culture of joint responsibility between employer and employee (Etuknwa et al., 2019). Etuknwa et al. (2019) suggest that key boosters of mental health and wellbeing in the workplace requires a holistic approach if possible, where managers, human resource (HR), occupational health and safety personnel, union representatives and employees work together in the decision-making of effective return to work programmes. This seems of particular relevance within the current COVID-19 pandemic to ensure a safe return to work of those employees affected and to retain them at work in order to minimise the risk of recurrent or prolonged sickness leave and its associated negative outcomes.

1.3. COVID-19 pandemic

COVID-19 presents a challenging scenario for a safe return to work following long-term sick leave, particularly amongst those employees with poor mental health wellbeing. The coronavirus outbreak has caused sudden and drastic changes to workplaces to ensure the safety of employees. Some employees may be returning to work remotely following sick leave, making isolation from the workplace a key concern. Other employees may experience (additional) anxiety and fear to return to work on-site even if a workplace is deemed to be COVID secure. Therefore, initiatives promoting a supportive and transparent return to work experience between the employee and their workplace is now more important than ever. Practical tips, good quality communication and tailored support, at both business and employee level, are key to get employees back to work safely and to protect their mental wellbeing, regardless of their reason for sick leave. Whilst a number of return to work toolkits have been developed to support employees to return to work after COVID-19, these have not focused on sick leave, but on the return of 'healthy' employees. The proposed study builds on previous return to work (RTW) toolkits designed by lead PI and will use the earlier needs analysis and evidence synthesis to guide and finalise a return to work (RTW) model to pilot with businesses. This research will generate new knowledge on the feasibility and effectiveness of a tailored RTW evaluated using a two-armed pilot randomised controlled study design.

1.4. Proposed study

The proposed study is part of a larger research programme by the Mental Health and Productivity Pilot, whose broader aims are a) to reduce the impact of poor mental health in the workplace and barriers to employability and productivity; b) to reduce stigma around workplace mental health; c) to deliver evidence-based, locally relevant, tested and sustainable workplace programmes to suit the needs of employers and employees.

This proposed study, known as work package 7, is a two-year project that will pilot test a return to work toolkit for employers and a return to work toolkit for their employees over an 12-month study period to support during the COVID-19 pandemic, the return to work of workers remotely or on-site, following sick leave due either to poor mental wellbeing or due to other reasons where poor mental wellbeing maybe a co-morbidity. Following on from the baseline evidence collected in the first phase of MHPP, a tailored return to work toolkit has been co-developed with employers and employees, involving skills training and guidance for those responsible for managing the sickness absence and return to work of employees (such as a line manager), and guidance, support and self-management techniques for employees.

1.5. Study Aims

The primary aim of this study is to pilot the employer and employee return to work toolkits in a two-arm randomised controlled (RCT) trial and assess the feasibility of a future large trial to test the effectiveness of the return to work toolkits in reducing the number of days of long-term sick leave (defined as eight or more days on sick leave). The pilot will also assess the likely outcomes of a main trial. Figure 1 outlines the study logic model.

1.6. Objectives

The objective of this pilot trial includes both process and research objectives. Analysis of the process objectives will allow for the feasibility of a larger RCT to be assessed.

1.6.1. Process objectives

1. To assess the willingness of organisations to take part (baseline) and the engagement of employers to stay in the pilot trial through the 12-month study period.
2. To estimate employee and line manager participant recruitment rates in both control and intervention groups (assessed at end of recruitment).
3. Explore any evidence of selection bias in participants recruited to the pilot from the control and intervention organisations (assessed by participant characteristics).
4. To estimate retention of participants in the research evaluation at each follow-up time-point across both control and intervention groups.
5. To assess implementation of intervention delivery, dose, fidelity engagement and adherence (defined as at least 60% download of the total toolkit by employees and line managers (or those with a responsibility for managing return to work), and at least 60% completion of the activities/checklist in total).
6. Determine the willingness and readiness of employers and their employees to adopt the proposed intervention in a manualised format (written as an instruction manual) but that is flexible enough to meet individual and organisational needs in different settings

1.6.2. Research objectives

The pilot trial will also provide a useful test of outcome data collection methods and provide information on the likely changes in these outcomes in the control and intervention groups. Whilst a main trial will provide the definitive test of the difference between trial groups on these clinical outcomes, the pilot has the following research objectives:

1.6.2.1 Primary outcome

1 Establish the likely changes in the total number of days of sick leave until partial/full return to work 6 months after baseline as a result of intervention to inform the planning of a larger trial and estimate the inter-cluster correlations for these outcomes.

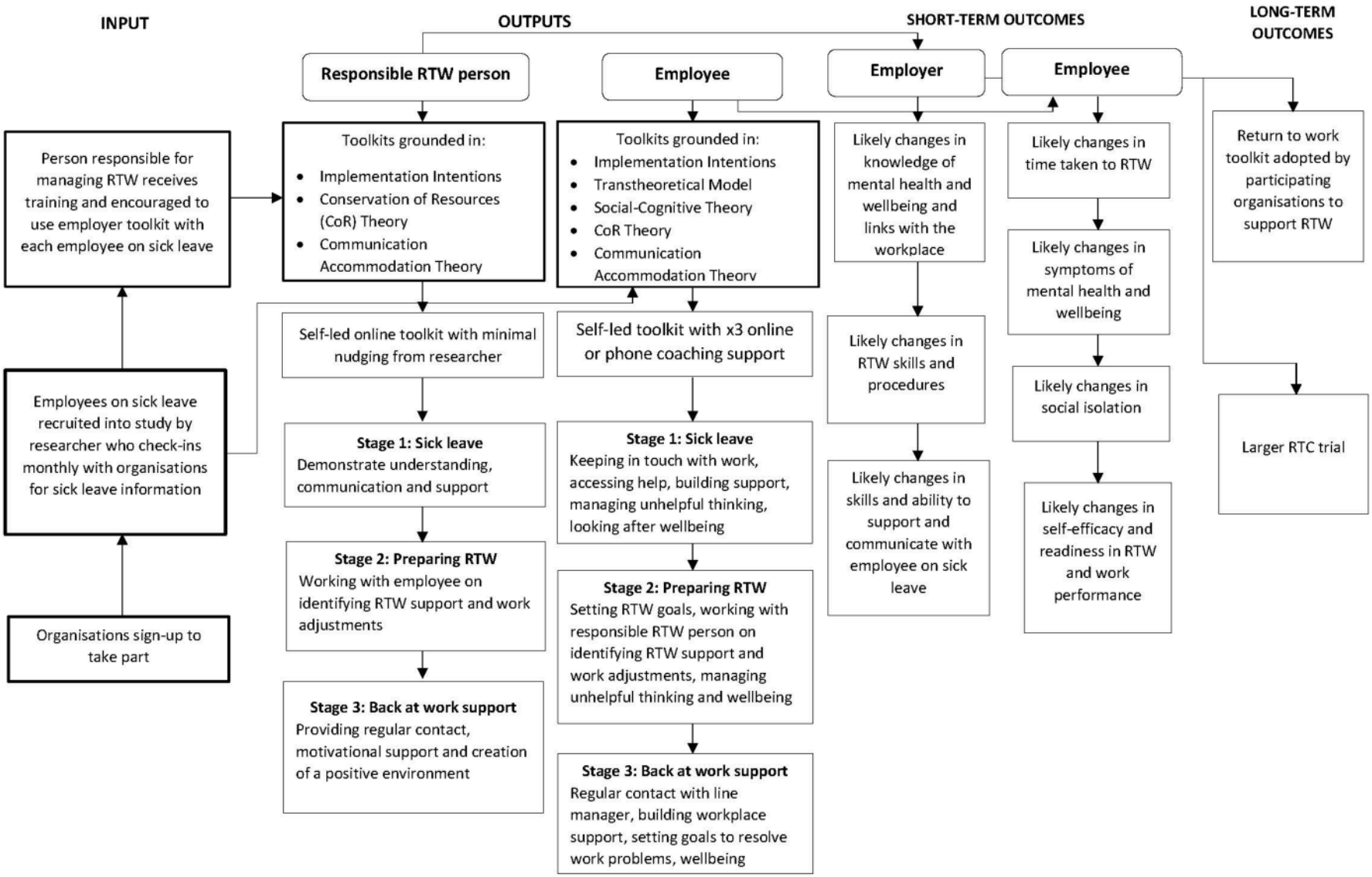
1.6.2.2 Secondary outcomes

2 To investigate likely changes in mental health (e.g. anxiety, depression).

3 To explore likely changes in confidence and readiness to return to work, quality of life and work productivity.

4 To provide an early estimate of the costs, both healthcare and societal costs, in both intervention and control groups.

Figure 1: Study logic model



2. Methods

2.1. Study design

This pilot study is a two-armed randomised controlled trial in organisations of different sizes and sectors. Each organisation are the units of randomisation (the clusters), with data collected from individual employees (the participants) on long term sick leave due to poor mental health or due to another reason but with a comorbidity with mental health. Data will also be collected from those with a responsibility of managing the return of an employee (secondary participants). This design overcomes the problem of contamination between the intervention and control arms and the problems associated with individually consenting and randomising employees to a trial where the employers may be managing the sick leave of two or more employees. A repeated measures design will be adopted, whereby employee participants will complete outcome measures at baseline, 3 months and 6 months. Each organisation's involvement in the trial is for 12 months.

2.2. Study setting

The study will take place in a wide range of organisational settings across the Midlands and will involve small (10 to 49 employees), medium (50 to 249 employees) and large (over 250 employees) enterprises as relevant.

2.3 Intervention content and intervention groups

The return to work intervention is a multicomponent intervention promoting early communication and support for the employee to reduce the number of days on long term sick and enable a successful return to work. The intervention comprises of two toolkits – an employer return to work toolkit manual and an employee return to work toolkit. Both the employer and the employee return to work toolkits are self-led interventions used by the employer (or manager) and the employee themselves. The guidance and resources in the toolkits for the employee and the employer mirror each other to ensure both receive the same messages and to encourage transparency.

The employer webinar training and the employer and employee toolkits are accessed through a secure website, with each participant having a password protected account. The toolkits include three step-by-step approaches to be used at different stages of the employees' return to work process: step 1) managing initial sick leave, step 2) preparing to return to work, and step 3) managing back at work. Additionally, the employee toolkit is supported by a coaching component and the employer toolkit is supported by an upskilling training webinar session. The employer toolkit has been developed with input from employers and managers from small, medium and large business and the employee toolkit has been developed with input from employees who are experiencing or have experienced low mental wellbeing (e.g. stress, depression or anxiety). Both toolkits have also been developed with input from the charity Mind as well as evidence from the scientific literature, and best practice guidelines for the UK (e.g. Health and Safety Executive guidelines).

The toolkits are grounded in several theories: Implementation intentions (Gollwitzer, 1999), Conservation of Resources (CoR) Theory (Hobfoll, 1989), and Communication Accommodation Theory (Giles et al, 1991). In addition, the employee toolkit is also grounded in the Transtheoretical Model (Prochaska and DiClemente, 1982) and the Socio-Cognitive Theory (Bandura, 1986).

Employees

Employees on sick leave will receive a step by-step action-oriented toolkit that provides guidance and support from initial absence to post return to work. Three workplace coaching sessions will be offered to employee by the project researcher either face to face or over the phone (depending on the social distancing guidelines). These will be delivered at three time points throughout the intervention: 1) At the start, to support making contact, to coach the participant in the use of the resources, to build a relationship with the participant and to direct the participant to external resources available in the toolkit; 2) at 2 months to coach them for preparation to return to work, or if they have returned to work, then to coach them in adjusting back to work, 3) at 3 months to either coach them for preparation to return to work, or if they have returned to work, then to coach them in adjusting back to work. The coaching sessions aim to motivate and support employees to use the RTW toolkit, to help them with any activities they might feel stuck with and to discuss their action plan to avoid any relapse. During these sessions, and as part of the process evaluation, the workplace coach will ask about what resources is the employee finding more useful and what are the benefits of using this toolkit.

To reinforce the message of having regular communication with the workplace whilst on sick leave, the employee will have the option to contact the workplace coach (i.e. project researcher) when needed using a texting service (Textmagic) to arrange a phone call. Additionally, the workplace coach will send reminders to the employee every two weeks, for them to continue using the toolkit during their sick leave and when they return to work

Employers

Employers will be offered a return to work upskilling training at the start of the intervention study, prior to recruiting employees on sick leave. The key workplace person (e.g. their line manager) responsible for managing an employee on sick leave will receive an employer version of the toolkit and provided with advice on when and how to use it with an employee. For those individuals who are managing more than one employee on long-term sick leave, they will receive a phone call and an email from the researcher at the start of each employee on long term sick leave, to remind them to use the toolkit.

2.2 Active Control group

Those organisations allocated into the control group will not receive any training or guidance. They will receive a detailed consultancy report evaluating their current return to work policies and procedures, access to the line manager training and hard copies of both toolkits at the end of the study.

2.3 Recruitment of organisations

Workplace return to work interventions in the UK can be challenging for a number of reasons:

- Some employers may not keep accurate records such as the reason for sick leave, making recruitment difficult.
- Employers may not wish to promote the study to employees for whom they think work might have caused their illness and subsequent sick leave.
- There might be very low numbers of employees taking long-term sick leave during the project in some organisations. Employees might be managing it in other ways such as through flexible working and/or sickness presenteeism.
- Some employers (mainly larger ones) might have very good RTW policies and practices and may not benefit from an RTW intervention.

A recent UK RTW intervention study by Madden et al (not yet published) recruited 7 large NHS Trust sites to take part. Over a 3-month employee participant recruitment period, they recruited a total of 24 participants of which 11 were randomised into the intervention and 13 into the control arm. To ensure we have enough uptake, our recruitment strategy has been designed to overcome the above described challenges and will target large, medium and small organisations.

First, organisations who express an interest in the study, will be asked about the prevalence of their long-term sickness absence data within the last 12-months (this timeframe maps our study recruitment period). Next, we will examine their RTW to work policies and practices for any overlaps or contradictions to our RTW toolkit. Those with at least 2 employees in small organisations, 4 in medium-sized organisations and 6 in large organisations taking long-term sick leave in the past 12 months and with no contradictory or overlapping RTW polices will be recruited to take part in the study.

We will ensure that there is a long recruitment period (from September 2020 to September 2021), that organisations are primed in advance of the study commencing through online kick-off meetings, engagement with project researcher and project manager, information in network newsletters, press releases etc. The researchers will contact the organisation every fortnight to ensure that any employees that have gone on sick leave and are eligible to participate in the study are recruited in a timely manner.

2.4 Participating organisations and individual participants

Within participating organisations, individual participants will be employees on long-term sick leave (≥8days) due to either low mental wellbeing or where low mental wellbeing may be a comorbidity; and either their employer or those with a responsibility of managing an employee on sick leave.

2.4.1 Inclusion criteria

Employee:

- To have been on sick leave for at least eight days and less than six weeks (42 days)

Employer:

- Be the responsible person in managing return to work of the employee (e.g. line manager, HR, another manager)
- Have no conflicting or overlapping RTW policies or practices with the intervention

2.4.2 Exclusion criteria

Employee:

- To be aged under 18 years of age
- On sick leave with a psychotic episode such as schizophrenia, or with substance abuse
- On sick leave whilst under formal investigation for misconduct or in the formal process of disciplinary action
- On sick leave being diagnosed with cancer and signed off work for at least six months
- On sick leave due to a neurological condition (e.g. multiple sclerosis, Parkinson, Dementia)

Employer:

No exclusion criteria

2.5 Outcome measures

For process outcomes and research outcome measures, survey data will be collected either using hard copy or online based platforms. Qualitative interview data will be collected either over the phone or using online conferencing facilities. Both full-return (defined for this study as working the same days or hours per week as before sickness absence in an identical or equivalent role for at least four weeks) and partial return to work (defined as working any number of hours in any role) data will be collected via text messages.

Process Outcomes

Process outcomes will determine if a future main trail is possible and desirable. We will carry out a detailed process evaluation informed by the Implementation Outcome Framework (IOF) (Peters et al, 2013; Proctor et al, 2011). This framework includes eight implementation outcomes (acceptability, adoption, appropriateness, feasibility, fidelity, implementation cost, coverage and sustainability). In addition, the Theoretical Domains Framework (TDF) (Michie et al, 2005; Cane et al, 2012), a widely used framework in behaviour change and implementation research, will also inform our process outcome data collection. Use of the TDF allows an in-depth exploration of the barriers and facilitators of implementing the trial. The data collection methods outlined below capture the process outcome information for the IOF and TDF.

Objective data collection

We will collect the following information from each participating organisation prior to randomisation:

- Summary of long-term sickness absence data for the past 12 months (only total numbers and % by reasons)
- Size and sector
- Copies of sickness absence policy and frameworks
- Copies of to work policy and frameworks
- Details on mental health training and support

Following randomisation, we will collect data during the 12 month study period on:

- Number of employees on sick leave (≥ 8 days) and their reasons
- Number of employees that employers have contacted to take part in the study
- Number of employees consenting to take part
- Number of employees using the toolkit (data collected at interviews and website use)
- Number of persons responsible for managing the sick leave and return to work of employees consenting to take part
- Number of persons responsible for managing the sick leave and return to work of employees attending the training
- Number of persons responsible for managing the sick leave and return to work of employees using the employer toolkit (data collected at interviews and website use)

Coverage (recruitment and attrition):

Where possible, data on reach of study participation advertisement, expressions of interests, recruitment, participation and drop-out for all participants.

Toolkit use /adoption.

The google analytics built into the website will allow us to record a number of different metrics such as number of visits to the site per day, behaviour of viewers once on the website (i.e. which pages they visited), where most of the traffic to the toolkit website came from, the percentage of returning participants etc.

Interview data collection

(Intervention acceptability, feasibility, fidelity and sustainability)

Intervention employees and managers/return to work contact:

- For intervention employee participants, short employee interviews will be conducted at each coaching session (at intervention start, 3 months and six months) to explore use of the toolkit.

- At six months (end of intervention), an interview will be conducted with both employee participants and line manager/return to work contacts to ask them about their engagement, usage and the effectiveness of the toolkit. In addition, other information (such as barriers/facilitators to implementation, functionality and interest in on-going usage) will also be explored.

Employers (intervention and control group):

- Short employer interviews (e.g. with HR, Health and Safety Manager) with intervention and control sites will be conducted three monthly intervals to explore any changes to policies or processes that may impact the study. These include a) sickness absence and return to work b) COVID-19 pandemic, and c) redundancies or organisational restructuring. Questions around study participation (e.g. identifying employees on sick leave, sending out study information, etc) will also be explored.

- At the end of 12 month study period, we will interview the relevant organisational stakeholder contact stakeholders (e.g. human resource contact/senior manager) to explore their perceived benefits of the intervention (engagement, usage, functionality and the effectiveness of the toolkit), as well as barriers/facilitators to implementation, interest in on-going usage, and whether the intervention could form part of any workplace return to work policies.

Intervention cost:

Costs associated with toolkit website build and delivery, training delivery, coaching sessions and other associated costs will be collected.

2.5.1 Primary research outcome measure

Participant employee measures (at baseline, three months, and six months)

Number of days of sick leave will be recorded from the employer and from the employee (self-report). Self-report data will be collected at baseline at 3 months and at 6 months (from control and intervention participants) in the online survey and will ask them to report if they are still on sick leave or if they are planning to return to work using several questions:

- Are you still on sick leave?
    - If yes, do you have an RTW date?
- If not on sick leave, when did you go back to work?
- How many hours are you currently working?
    - Is this the same as before your sick leave?

For those who have returned to work, we will ask them for the date of their first day back at work (and whether it is a partial or full return). The last data collected will be at 6 months post randomisation.

2.5.2 Secondary research outcome measures

Employee measures (at baseline, three months, and six months)

- *Self-report mental health*: the 9-item Patient Health Questionnaire (PHQ-9; Kroencke et al., 2001), and the 7-item General Anxiety Disorder (GAD-7; Spitzer et al., 2006) will be used to measure depression and anxiety, respectively. The PHQ-9 is used by GPs and practitioners involved in the Improving Access to Psychological Therapies (IAPT) initiative, giving us an opportunity to compare the outcomes of this study directly with routine care. Both measures accurately reflect improvement and worsening of symptoms of depression and anxiety.

- *Return to work measures:* Expectations about length of sick leave will be asked using one question from Aasdahl et al (2018) "For how long do you believe you will be on sick leave from today?" with six response options "not at all", "less than 1 month", "1–2 months", "2–4 months", "4–10 months" and "more than 10 months". The Lagerveld et al (2010) 11-item Return to Work Self-Efficacy Scale and the Franche et al (2007) 13-item Readiness to Return to Work will be used to assess confidence and readiness to return to work. For those who have returned to work the 9-item Readiness to Stay at Work Scale (Franche et al., 2007) will be used.
- *Workplace support and communication:* 6-item Workplace Health Communication Scale (Yarker et al, no date) will be used to assess quality of communication between the employee, employer and organisation.
- *Work outcomes:* For those who have returned to work at 3 months and 6 months, work productivity will be measured using the Work Productivity and Activity Impairment: General Health v2.0 (WPAI:GH; Reilly, Zbrozek & Dukes, 1993). The WPAI:GH yields four type of scores: '*Absenteeism*', '*Presenteeism*', '*Work productivity loss*' and '*Activity Impairment*'. A 1-item job satisfaction scale will be used to assess satisfaction (Nagy, 2002).
- *Intention to use toolkit:* 4-item Toolkit Use (Yarker et al., no date), will be used to assess motivation and engagement for those in the intervention group. These questions will be asked at each coaching session.
- *Quality of life:* Health-related quality of life will be assessed using the EQ5D-5L (Herdman et al., 2011).
- *Demographics and other measures:* we will also collect basic demographic information for each participant including their date of birth, ethnicity, and highest level of education. The average wage for each employee will be identified using UK Standard Occupational Classification coding and annual earnings data for each job type. Employees will also be asked if they are the main wage earner. Information on medical diagnosis of health conditions, prescribed medication use and other current therapeutic treatments for mental health will be collected (adapted from Peveler et al, 2005).

  At six months only, participants will also be asked what actions their workplace contact (i.e. person responsible for managing their return) carried out to support their return to work. The line manager behaviour questionnaire (Yarker et al., 2010; Munir et al., 2012) will be adapted for this purpose.

Survey measures for line manager/ return to work contact person

At baseline:

- *Mental Health and RTW experience*: Those with responsibility for RTW will asked about their experiences with mental health (1-item, Yarker et al, no date) and 2-item training question (1-item, Yarker et al, no date) and a 1-item question of long0term sickness absence and return to work management experience.
- *Demographics:* Data on age, gender, ethnicity, job role and tenure will be collected.

At six months:

- Participants will also be asked what actions they carried out to support the return of their employee. The line manager behaviour questionnaire (Yarker et al., 2010; Munir et al., 2012) will be adapted for this purpose.

Table 1: Schedule of process outcome measures across intervention period

	Baseline	Month 1	Month 2	Month 3	Month 4	Month 5	Month 6
Long-term sickness absence data for the past 12 months	✔						
Frameworks (sickness absence policy, return to work policy, mental health training and support)	✔						
Number of employees on a) sick leave (≥ 8 days) and their reasons, and b) that employers have contacted to take part in the study	✔ Fortnightly →	✔	✔	✔	✔	✔ →	✔ Continuing to end of recruitment period (e.g. 18 months)
Number of persons responsible for managing the sick leave and return to work a) consenting to take part, b) attending the training	✔						
Number of persons responsible for managing the sick leave and return to work using the employer toolkit	✔			✔			✔
Toolkit use (employer and employee)	✔						✔
Qualitative interviews (e.g. toolkit engagement, usage, personal or organisational changes during intervention, barriers, facilitators)							✔
Survey data (e.g. toolkit use, actions taken)							✔

Table 2: Schedule of research outcome measures

	Baseline	Month 1	Month 2	Month 3	Month 4	Month 5	Month 6
Number of days on sick leave/days taken to RTW	✔	✔	✔	✔	✔	✔	✔
Mental health status	✔			✔			✔
Return to work measures	✔			✔			✔
Workplace support and communication	✔			✔			✔
Work outcomes (for those who have returned to work)	–			✔			✔
Intention to use toolkit	✔			✔			✔
Quality of life	✔			✔			✔
Demographics	✔			✔			✔

2.6 Randomisation

In this pilot, RCT organisations will be stratified only by size but in the main trial, organisations would also ideally be randomised by sector. To avoid study contamination, organisations will be randomised into the intervention or active control group after baseline organisational measures are taken using a 1:1 ratio of intervention to active control group. Randomisation will be carried out by computer-generated randomisation stratified by organisational size (small, medium or large).

Participating organisations will be consented into the study by the project researcher who will then contact the key contact person within each organisation (e.g. HR or the employer in small organisations) on a monthly basis to ask if any employee has gone on long-term sick leave within the last month. Where an organisation identifies an employee on sick leave (≥8 days), the researcher will go through the employee inclusion criteria with organisation contact person. Employees who meet the criteria will be contacted by the organisation contact person to promote the study and to send them the relevant study information (letter of invitation, participant information leaflet, consent form). Those interested in taking part will be encouraged to contact HR or the researcher directly either by phone or email, who will answer any questions over the phone and support those who need it to complete the consent form.

Consented employees will be allocated to either the intervention or active control group based on the randomisation of their participating organisation. For the intervention participant, their key contact person for managing their sick leave will be contacted by the researcher and encouraged to use the employer return to work toolkit. Baseline data will be collected from each employee prior to either being given the RTW toolkit (intervention group employee) or supporting information (active control group employee). The project researcher will also inform each intervention participant's manager/employer to use the employer RTW toolkit. The participant employees and employers will not be blinded in group allocation.

The project researcher will keep in regular touch with each participant throughout the study period and may incentivise compliance with all data collection. We will also use the coaching as 'keeping in touch' points with each intervention participant to encourage engagement with the resources.

2.7 Study procedure

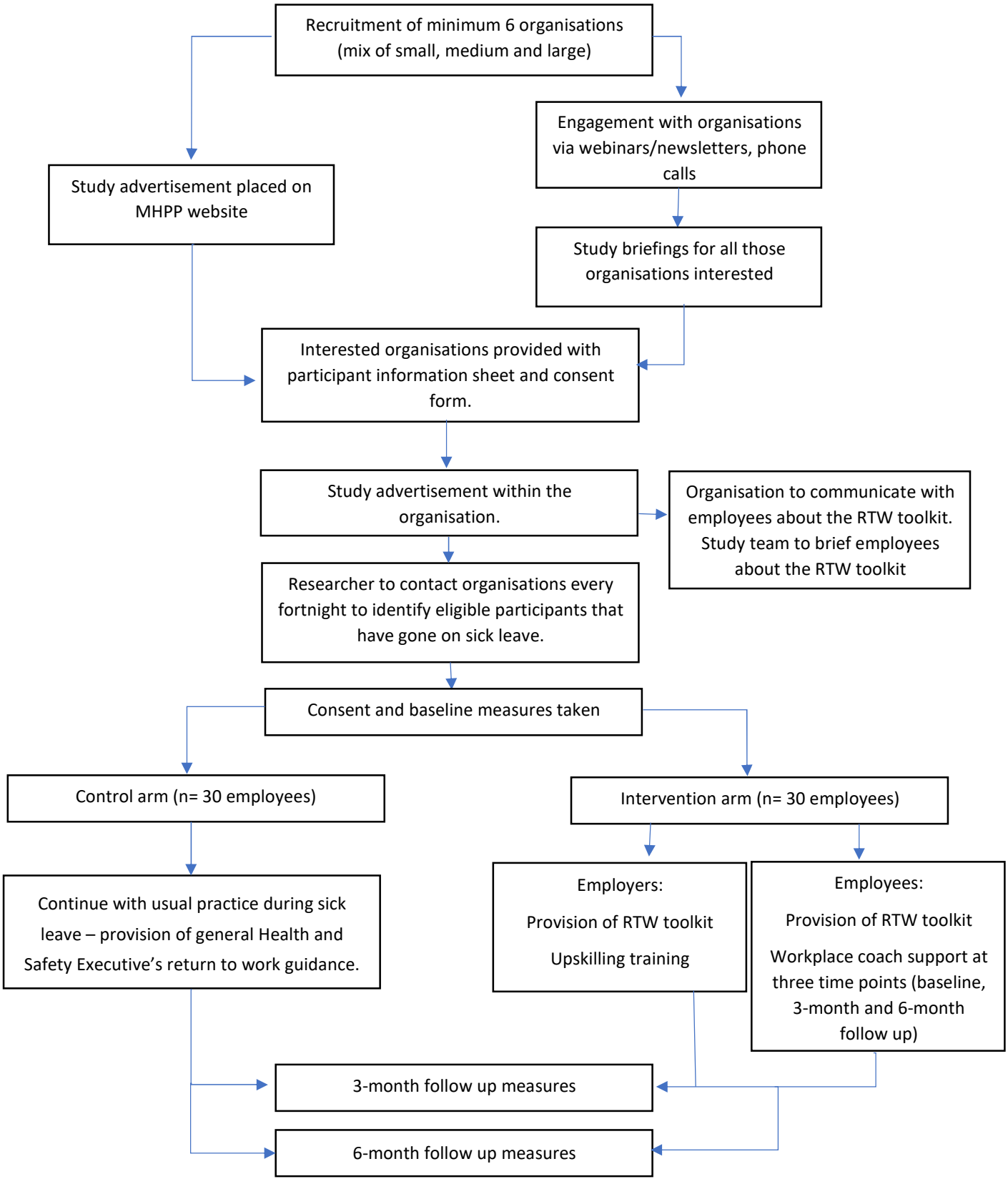
Participants will be provided with a written consent form that they will be requested to sign prior to participating in the study. To comply with the GDPR guidelines they will be provided with two copies of the form, one for them to keep and the other one to be stored as part of the study file. Inform consent will be

conducted according to ethical guidelines to ensure participants fully understand their participation in the study.

Following NICE guidelines, the RTW intervention will be offered to employee participants between the 8th day of sick leave and up to six weeks into a period of sickness absence (NICE, 2009). Intervention participants will be given a code to access the toolkit online. The intervention will be delivered to employees until return to work (RTW) or 6 months (last follow-up) from when the employee has gone on sick leave. The primary outcome of the intervention will be assessed monthly after randomization at the worksite level using 1.1 ratio approach (approximately 14 organisations in the intervention arm). For the primary outcome, we will contact (text message) the employees from the control and intervention group on monthly basis and will ask them to report if they are still on sick leave or if they are planning to return to work. For those who have returned to work, we will ask them for the date of their first day back at work (and whether it is a partial or full return). Secondary outcome measures of the intervention will be assessed at 3 timepoints (within 2 weeks of being on long-term sick leave, at 3 months and at 6 months).

Absences of one week or less are self-certificated in the UK, and fit notes provided by a general practitioner are unlikely to be practically available until the second week of absence (i.e. by day eight of absence). It could be argued that contact with an employee at two weeks of sick leave is too early in the stage of the sick leave to determine whether this may result in prolonged long term sick leave (i.e. two months or more) and therefore would be meaningless, and possibly harmful, since the employee may not be well enough to consider return to work plans for the future. On the other hand, the early contact with an employer in the initial sick leave phase would sustain the contact and possibly minimise the risk of developing very prolonged long-term sick leave. Based on good practice of early contact between the employee and employer, we will start the intervention at by the eight day of absence into sick leave and no later than six weeks (42 days). Figure 2 demonstrates the flow of the study participants from start to finish.

Figure 2: Study flow diagram



2.8 Sample Size

As this is a pilot study, a sample size is not calculated. We will enrol 60 participants (employees on sick leave) into the study with 30 participants in each arm (intervention and control group) during our six-month recruitment period. To allow 30% for participant drop out, missing data and lack of employer engagement, we will recruit 40 participants in each arm, recruiting a total of 80 employees. To reach our recruitment target, a minimum of 6 organisations of various sizes (small, medium and large) and sector, will be enrolled onto the study with 3 organisations randomised into each arm.

2.9 Definition of End of Trial

The end of trial is the date of the report submission – 30th June 2022. Data collection will finish on the 31st May 2022.

2.10 Discontinuation/Withdrawal of Participants from Study Treatment

Each participant and/or organisation has the right to withdraw from the study at any time. In addition, the investigator may discontinue a participant from the study at any time if the investigator considers it necessary for any reason including:

- Significant protocol deviation
- Significant non-compliance with the outcome measurements
- An adverse event which requires discontinuation of the study or results in inability to continue to comply with study procedures
- Consent withdrawn
- Lost to follow up

Withdrawal from the study will result in exclusion of the data for that participant from analysis if the results of the study have not been processed, at which point it will not be possible to withdraw individual data from the research. The reason for withdrawal will be recorded by the researcher. If the participant is withdrawn due to an adverse event, this will be reported to the ethics department within Loughborough University.

3 Analysis Plan

Since this is a pilot trial, the analyses will focus on describing the full process measures in order to decide if a main trial is feasible and desirable in addition to finalising the sample size for a future main trial.

Process outcomes:

- The number of organisations agreeing to participate in the trial will summarised in terms of their size, sector, sick leave and RTW polices and number of employees who were on long term sick leave in the past 12 months prior to the start of the study.
- The number of employee participants identified on long term sick leave and the number recruited into the study will be reported, along with the number of participants followed up at each time-point. Withdrawals (and where possible, reasons for withdrawals) will be reported. A priori, we have defined a success criterion of 50% of the total number of participants invited to be recruited to the research evaluation to make a main trial feasible. We will consider a rate of 60% of those staying in the trial at 6 months follow-up as satisfactory. We will provide the point estimate of the proportion and its 95% confidence interval (CI).
- Difference in recruitment uptake rate and follow-up rates at each time point will be compared between the intervention and control arms.
- As organisations of different sizes are taking part, it is likely there will be some imbalance between participants in each treatment arms on one or more baseline characteristics. Baseline comparisons will be carried out to detect any substantial differences between participants recruited from the control and intervention arms. This will be done by scrutinising the baseline table for any serious imbalances in observable baseline variables and the trends of the imbalance if any. The recruitment rates will also be estimated and compared between the control and intervention arms. We will examine the size of any imbalances and decide if there is evidence of systematic selection bias in the types of patients being recruited in control versus intervention arms.
- Key baseline characteristic will be compared between those participants followed up and those lost to follow-up at each timepoint.
- Intervention fidelity will be assessed by the log-in and downloads of the toolkits. Successful adherence is defined as at least 60% download of the total toolkit by employees and employers (i.e. those with a responsibility for managing return to work), and at least 60% completion of the activities/checklist in total.
    - Qualitative data for the process evaluation will be recorded, transcribed and downloaded using NVivo8, where it will be coded following the principles of thematic analysis.
    - Survey data for the process evaluation will be summarised using means, standard deviations, medians and ranges for continuous variables and counts and percentages for categorical variables.

Research outcomes:

Analysis will be conducted for the research outcomes, but this will be treated as exploratory and will mainly be descriptive.

- A baseline table (descriptive statistics and frequencies) will compare the demographic and clinical characteristics (gender, age, education, number of days on sick leave, mental health status, readiness, intention and self-efficacy to return to work, work support, communication, performance at work, sleep, and physical activity) between the two arms.
- We will summarise both cluster (worksites)and participant level baseline characteristics using means, standard deviations, medians and ranges for continuous variables and counts and percentages for categorical variables.
- As this is a pilot trial, no emphasis will be put on the p values for any inferential statistical tests conducted. Statistical analysis will be carried out on an intention to treat basis with missing outcome data being imputed using multiple imputation.
- A mixed effect model, which allows all available data at all the three time-points to be used and account for missing data and clustering effect, will be used to estimate a two-sided 95 % CI to show a reliable range for the true difference in the primary outcome i.e. number of days taken to return to work (partial or full) between intervention and the control arms. The model will be adjusted for key employee baseline characteristics (age, gender, education, wage, ethnicity, mental health symptoms, manual/office based work) and a random effect for the organisations and will include a intervention-by-time interaction to obtain the estimates of intervention effect (and 95% CI) at each follow-up (3 and 12 months).
- Statistical analysis will be carried out on an intention to treat basis with missing outcome data being imputed using multiple imputation. In order to explore the extent and patterns of missing outcome data, we will report the proportion of missing values per item, proportion of participants who complete all items on the questionnaire and the proportion of respondents who answer at least 50 % of the items in a scale. The proportion of missing data will also be reported for the other key outcomes and compared between the participants from intervention and control practices.
- Analyses of the secondary outcomes will be performed similarly and reported with caution and in relation to the overall pattern of results considering multiple testing. The assumptions of each analysis will be assessed, and alternate parameterisations will be considered where appropriate.

Power calculation:

- The pilot data will provide information on the parameters needed for a realistic sample size calculation (mean, standard deviation and treatment effects of the primary outcome for the two arms) for a future, main cluster RCT.

Health economic analysis:

The economic analysis will be exploratory, with the aim to inform the design of a full cost utility analysis alongside a future main trial. Data on costs will be sought from all participants and results will be presented taking into account employee-incurred costs and productivity losses. Analyses will be mainly descriptive, and all costs and outcomes will be summarised using means and 95 % confidence intervals.

- Healthcare resource used will be collected using self-completed questionnaires at baseline, 3 and 6 months, with a recall period of 3 months in each. Questions will ask employees to recall GP consultations, visits to healthcare professionals, outpatient appointments, investigations or treatments and inpatient stays related to the index condition (adapted from Peveler et al, 2005). Participants will be asked to distinguish between NHS and private practice visits.
- Resource used for the intervention will be directly recorded and costs attached, staff time (e.g. coaching sessions, training sessions), materials (posters, flyers, referral forms, website set-up and maintenance, toolkit printing) and training sessions.
- Costs will take into account both absenteeism and presenteeism and will utilise self-report data on employment status, occupation and time off work and reduced productivity at work (presenteeism).
- All employees will be asked to complete the 5-level version of the EuroQoL-5DL (EQ-5DL) questionnaire at baseline, 3 months and 6 months in order for the quality-adjusted life years (QALYs) over the 6-month time period to be calculated for each participant. The QALYs combine information on health-related quality of life and survival.
- Productivity costs will be calculated using data collected on absence from the number of days taken to return to work.
- Using the human-capital approach(which assumes that the value of lost work is equal to the amount of resources an individual would have been paid to do that work) the self-reported days of absence will be multiplied by the respondent-specific wage rate.

4 Safety Reporting

4.2 Adverse Event

Due to the nature of this study we do not anticipate any adverse events to occur; however should any arise, we will follow Loughborough University guidelines for managing and reporting adverse events, serious adverse events and suspected, unexpected serious adverse reactions which follow those outlined in good clinical practice guidance.

5 Quality Control and Quality Assurance Procedures

The study will be conducted in accordance with the current approved protocol. Data will be evaluated for compliance with the protocol and accuracy in relation to source documents.

5.2 Codes of Practice and Regulations

5.2.1 Ethics

Full ethical approval will be sought from Loughborough University, who are leading this work package. The work package does not involve recruitment of patients, NHS ethics approval is not anticipated. However, if we recruit NHS Trusts as an employer organisation, R&D approval will be sought from the relevant trusts.

5.2.2 Sponsor Standard Operating Procedures

Sponsorship for the study will be provided by Loughborough University. All relevant Sponsor SOPs will be followed to ensure that this study complies with all relevant legislation and guidelines.

5.2.3 Declaration of Helsinki

The Investigator will ensure that this study is conducted in full conformity with the current revision of the Declaration of Helsinki (last amended October 2000, with additional footnotes added 2002 and 2004).

5.2.4 Approvals

For participating NHS organisations, once Sponsor authorisation has been confirmed, the protocol, informed

consent form, participant information sheets and any proposed advertising material will be submitted to an appropriate Research Ethics Committee (REC), regulatory authorities and host institution(s) for written approval. Once Sponsor authorisation has been confirmed, the Investigator will submit and, where necessary, obtain approval from the above parties for all substantial amendments to the original approved documents.

5.2.5 Participant Confidentiality

The research team will ensure that the participants' anonymity is maintained. The participants will be identified only by initials and a participant's ID number on the questionnaires and any electronic database. All documents will be stored securely and only accessible by trial staff and authorised personnel. The study will comply with the Data Protection Act which requires data to be anonymised as soon as it is practical to do so.

5.2.6 Data processing

Personal data will be processed on the public task basis. For further details on the data protection legislation see: https://ico.org.uk/your-data-matters/ Under the General Data Protection Regulation (GDPR)

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Appendix - Timeline

Deliverable	Date
• Refine all measures and finalise pilot institutions	Y2 Month 2 (September 2020)
Update report: • Pilot site engagement for expressions of interest • Any tweaks to protocol identified • Minutes of Project Delivery Group meetings	Y2 Month 4 (October 2020)
Update report: • Pilot site engagement and data collection • Numbers of participants engaged • Description of data collected (amount, quality) and any relevant feedback and tweaks to protocols. • Minutes of Project Delivery Group meetings	Y2 Month 7 (January 2021)
Update report: • Pilot site engagement and data collection • Numbers of participants engaged • Description of data collected (amount, quality) and any relevant feedback and tweaks to protocols. • Any initial baseline results • Minutes of Project Delivery Group meetings	Y2 Month 10 (April 2021)
Update report: • Pilot site engagement and data collection • Numbers of participants engaged • Description of data collected (amount, quality) and any relevant feedback and tweaks to protocols. • Final baseline results • Initial follow-up results • Minutes of Project Delivery Group meetings	Y3 Month 2 (August 2021)
Final WP report	Y3 Month 6 (June 2022)