RESEARCH PROTOCOL

Home Goals: A randomised controlled trial to improve mental and physical health and well-being in young people

Short title of the study	Sponsorship and funding details
Home Goals	*Sponsor organisation:* Rotherham Doncaster and South Humber (RDaSH) NHS Trust *Funders:* RDaSH NHS Trust, Yorkshire Sport and Active Humber
Protocol version and date	**Approval and registration details**
(v2.1) 23/04/2021	*Ethics approval reference:* [TBC] *Controlled trial registration:* [TBC]

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Contents of the study protocol

1. Synopsis of the study	
Short study title	Home Goals
ISRCTN registration no.	[TBC]
Study Design	Multi-site randomised controlled trial
Setting	School children attending schools across the geography of Rotherham Doncaster and South Humber (RDaSH) NHS Foundation Trust
Study Participants	11-18 year olds who attend school in the RDaSH locality, who are at risk of, or are suffering from low-level mental health problems
Aim	To evaluate if access to psychoeducation and physical activity intervention improves young people's health and wellbeing
Objectives	▪ To assess changes in mental wellbeing ▪ To assess changes in physical wellbeing ▪ To assess completion and dropout rates
Primary outcome	Depression which is measured using the PHQ-9 modified for Adolescents (PHQ-A)
Interventions	A 6-week, psychoeducation and physical education course consisting of online live psychoeducation sessions and physical activity sessions
Randomization and data collection	Consenting participants will be randomly assigned to two groups; 1 and 2. Participants in both groups will be asked to complete outcome measures at an initial baseline assessment, after which only participants in group 1 will access a 6-week intervention (*controlled phase*). Next, group 2 will access the intervention during a 6-week period (*full implementation phase*). Finally, we will collect further outcome measures 6 months after both groups have completed the intervention (*follow-up phase*).
Planned Sample Size	Minimum recruitment target of 192 participants, expecting 30% attrition.
Data analysis method	1. Trial data will be summarised using a CONSORT diagram and analyses will be based on *intention-to-treat* principles. 2. The primary analysis will compare between and within-group differences in PHQ-A at baseline and 6 weeks, using ANOVA. 3. Secondary analyses: between and within-group analyses will be conducted for GAD-7 and the physical activity measure at baseline and 6 weeks using ANOVA. 4. Between-group and within-group effect sizes will be calculated using Cohen's *d*. 5. Completion / dropout rates will be compared between groups using chi-square analysis.
Study Period	18 months (12 months active study period, plus 6 months analyses and dissemination)

2. Background and rationale

Mental health problems cause huge public health burden in adolescents globally, as evidenced by a 20% prevalence (Belfer, 2008; World Health Organization (WHO), 2005). In the UK, the demand for Child and Adolescent Mental Health Services (CAMHS) services is at an all-time high and recent research shows children and young people referrals have increased by 26% in five years (Crenna-Jennigs & Hutchinson, 2018). Furthermore, 50% of children and young people that are assessed, wait more than 18 weeks to start treatment and over 3% wait over 12 months (Crenna-Jennings & Hutchinson, 2018).

For the treatment of depressive symptoms, existing literature reports the benefits of psychoeducation based interventions. Tursi, Baes, Camacho, Tofoli & Juruena (2013) concluded that psychoeducation is effective in improving the clinical course, treatment adherence, and psychosocial functioning of depressive patients. In a systematic review of 15 studies of psychoeducational interventions on depression conducted by Jones et al. (2018) it was ascertained psychoeducational interventions can have a role in preventing and managing adolescent depression as a first-line or adjunctive approach, however the limited number of studies, heterogeneity across formats and evaluation and inconsistent approach to defining a psychoeducational intervention, make it difficult to compare programmes and measure overall effectiveness.

Methods of administering the psychoeducational interventions have also been investigated; in a study looking at the effects of a Stress Control course with allied delivery by sports organisation (in this instance the Gaelic Athletic Association), Hayes et al. (2020) identified that participants who engaged with the intervention had identified positive lifestyle changes since completing the course, from generic self-care to making specific changes directed towards combating stress. Further, greater participation by participants (especially in male participants) was attributed to the delivery of intervention by sports professionals.

The WHO (2018) recommends that young people engage in at least one hour of moderate physical activity a day. In a recent publication by the Health Behavior in School-Aged Children (HBSC; Brooks, Klemera, Chester, Magnusson & Spencer, 2020) found that activity levels among young people are poor, with only 15% reporting being physically active of at least an hour a day, and in fact there has been a decline in physical activity reported by young people since 2002.

Research has demonstrated that physical activity may provide psychological benefits (Brown, Pearson, Braithwaite, Brown & Biddle, 2013; Dishman et al., 2006). Compared with traditional interventions, such as psychotherapy, psychosocial, and pharmacological interventions, physical activity has few side effects and is relatively cost-effective (Liu, Wu & Ming, 2015). Moreover, physical activity can be self-sustaining (Larun, Nordheim, Ekeland, Hagen & Heian, 2006), therefore reducing the need for future interventions. A growing literature suggests that physical activity can improve mental health (Hassmen, Koivula & Uutela, 2000; Penedo & Dahn, 2005), including depression, anxiety, self-esteem, anger, stress and so on (Alpert, Field, Goldstein & Perry, 1990; Babyak et al., 2000; Davis et al., 2011; Holley, Crone, Tyson & Lovell, 2011).

Recent research has demonstrated the importance of good physical health in maintaining good mental health for young people and adolescents (Biddle, Ciaccioni, Thomas & Vergeer, 2019). For example, vigorous physical activity has been shown to be a protective factor (OR = 0.78, 95%CI: 0.67–0.91) in urban adolescents (Piche, Huynh & Villatte, 2019). Physical activity has a huge potential to enhance our wellbeing. Even a short burst of 10 minutes' brisk walking increases our mental alertness, energy and positive mood. Physical activity plays an important role in children's cardiovascular health, abstract musculoskeletal health, mental and behavioural health, and physical, social, and cognitive development (Lobelo, Muth, Hanson & Nemeth, 2020).

Evidence suggests that physical activity improves depressive symptoms (Cooney et al., 2013; Nystrom, Neely, Hassmen & Carlbring, 2015), whilst decreased physical activity increases vulnerability to the development of depressive symptoms (Aberg, et al., 2012, Carroll, Blanck, Serdular & Brown, 2010;

Hamer, Molloy, de Oliveira & Demakakos, 2009). In two recent meta-analyses involving 40 and 38 studies respectively, it was found that physical activity was negatively associated with depressive symptoms (Korczak, Madigan & Colasanto, 2017; Liu et al., 2015).

A further meta-analysis of the use of physical activity to improve depression symptoms, found that the methodology is often problematic due to the low quality of the papers (Bailey, Hetrick, Rosenbaum, Purcell & Parker, 2018). However, physical activity was found to improve depressive symptoms in those aged 15-25 years. This paper highlights the need for stricter controls in studies, which this randomized control trial allows.

The combination of physical activity and psychoeducation in treatment of stress and depressive symptoms has shown to be superior than merely exercise alone. In a study looking at Dutch Women of low socio-economic status; exercise and psychoeducation compared with only exercise and a waiting list controlled condition (van der Waerdena, Hoefnagelsa, Hosman, Souren & Jansen, 2013) no indications were found that the exercise without psychoeducation reduced depressive symptoms and stress levels in the short or long term.

According to HSBC England National Report (Brooks et al., 2020) the most popular reasons for undertaking physical activity were to have fun and to improve health, therefore it seems logical to combine the most popular reasons to participate in physical activity with the significant findings of physical activity improving health and well-being adolescents to create an intervention that combines physical activity with psychoeducation to address depression and anxiety in adolescents.

This study is based upon the concept of Safety Nets which was developed as a face-to-face physical activity and psychoeducation intervention programme aimed at 11-18 year olds who are suffering from anxiety. The Safety Nets intervention was provided on site at either a football or rugby stadium. Both the psychoeducation and physical activity sessions lasted for an hour, and the physical activity sessions were taken by members of the local sports team/staff. However, due to the COVID-19 pandemic, the face-to-face sessions were no longer possible, therefore “Home Goals” was developed. Home Goals is an intervention that aims to ensure the safety of staff and participants by completing the sessions over video conferencing software. The team recognised that two hours may be too long for participants to engage when they are at home with a wealth of distractions, so the whole intervention time was halved.

The project aims to create therapy groups for children to improve their mental and emotional wellbeing. Each therapy group runs for one hour after school for six weeks, one half an hour focussing on physical activity (led by a local sports club) and another half an hour focusing on psychoeducation, led by NHS staff (e.g mental health nurse, psychiatrist, psychologist, Psychological Well-being Practitioners). The physical health aspect of the groups encompasses a broad range of physical activities, adapted to try at home. The groups also enable young people to learn about how and why anxiety and depression occur, and how we can learn ways of managing them.

This project is especially crucial given the nature of the COVID-19 pandemic, and ensuring the safety of staff and patients, by allowing the delivery of the interventions over video-conferencing software.

3. Objectives and Hypotheses

3.1. Primary Objective

To assess changes in mental wellbeing

3.2. Secondary Objectives

- To assess in attitudes towards physical activity
- To assess completion and dropout rates

3.3. Hypotheses

A) Exposure to the intervention will be associated with significantly lower mean score of depression and anxiety by comparison to a waitlist (delayed intervention) control group

B) After the control group is exposed to the intervention, there will be no significant differences in mean depression and anxiety level between the two groups (immediate intervention group, delayed intervention group)

C) Mean depression and anxiety severity for all participants at the end of the 6-month follow-up period will be significantly lower than baseline severity (prior to intervention), but not significantly different to end-of-treatment severity, indicating maintenance of gains

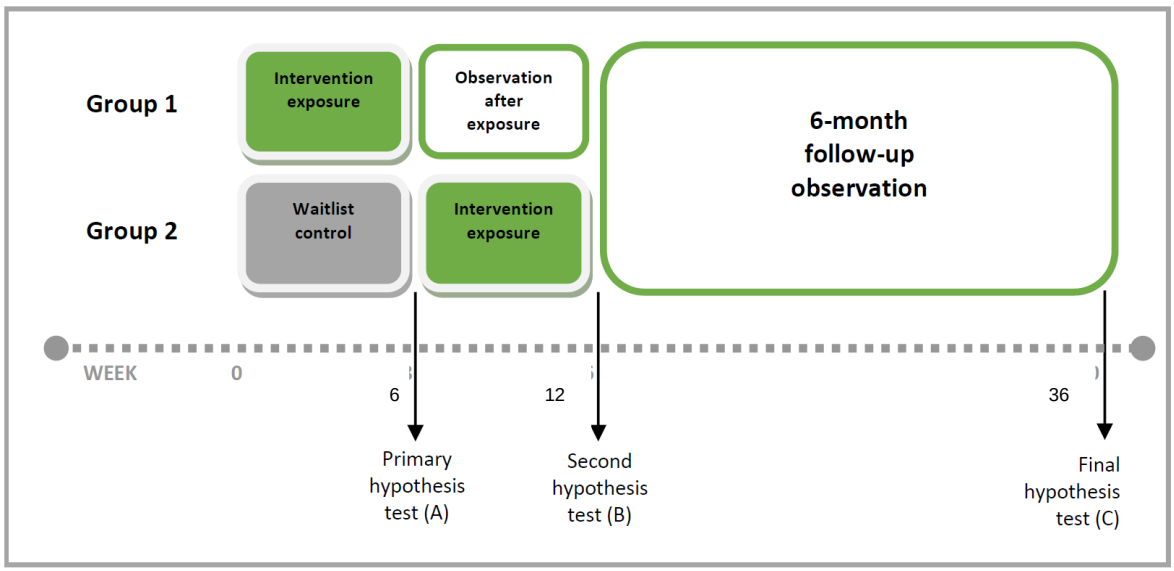
D) Attitude towards physical exercise will significantly improve following the intervention, and be maintained at the 6-month follow-up period.

4. Study design

This will be a pragmatic, stepped wedge, open-label, randomised controlled trial. Consenting participants will be randomly assigned to two groups, by a research assistant using a computerized randomization algorithm (applying a simple 1:1 randomization schedule). Participants will take part in one of the two 6-week interventions, depending on their group assignment. They will complete an online survey with standardised measures at baseline (prior to starting the interventions), after 6 weeks (after group 1 has finished and prior to group 2 commencing), after 12 weeks (post-treatment) and finally after 6 months (follow-up). All measures will be completed online using an industry-standard survey system which automatically sends email reminders to consenting participants.

The interventions will be delivered using an online approach; weekly online video-conference sessions involving half an hour of psychoeducation and half an hour of physical activity. Both interventions will involve a total of six 1-hour sessions delivered once per week using video-conferencing software that can involve large groups of participants. The study will be carried out in four phases, which are illustrated in Figure 1.

Figure 1. Trial design and measurement time-points



4.1. Setting and participants

This study will involve adolescents aged 11-18 years old who are on a waiting list for CAMHS services, or have been highlighted by School Champions and School nurses, and are adolescents who would potentially benefit from some low level psychological intervention. The participants will live in the areas covered by RDaSH. Suitable participants should require low level intervention for support in;

understanding their emotions, coping with low mood, anxiety or stress, and learning strategies for improving their overall mental health and wellbeing.

Inclusion criteria

- Any child aged 11-17 (we will accept participants who turn 18 in the trial period) who may benefit.
- Children must attend a school within the Rotherham, Doncaster, North Lincolnshire or Bradford locality

Exclusion criteria

- Adolescents who are already in receipt of psychological therapy
- Adolescents with a diagnosed condition (such as Autism Spectrum Disorder, learning disabilities, severe depression)
- Adolescents experiencing suicidal ideation
- Adolescents with no access to electronic devices
- Anyone who has participated in either Home Goals or Safety Nets before
- Anyone who is 18 at the time of recruiting (we will accept if they turn 18 over the trial period – but not before the trial starts)

4.2. Interventions

Home Goals is designed as a low intensity psychoeducational intervention for young people between 11 years and 18 years of age. The sessions combine a physical exercise activity for 30 minutes, led by Scunthorpe United Football Club and Bradford City FC, followed by 30 minutes of psychoeducational information led by CAMHS, the School Nursing service and taken by clinicians trained to provide group therapy.

The programme runs as a one hour session, once a week, for six weeks. The outline of the sessions is as follows:

- Half an hour psychoeducation based on the ACT principles, and looking at why we experience the emotions we do, and how we can control them
- Half an hour light physical activity run by a sports professional

4.3. Measures

Primary outcome measure

The PHQ-A is a nine-item questionnaire; each answered on a 0 to 3 Likert scale. Items cover different aspects of depression and are worded negatively. Item scores are summed to produce a total score (range: 0 to 27), where higher scores indicate greater levels of depression. Psychometric testing has indicated that this measure was valid, reliable and acceptable measure of depression in adolescent respondents (Johnson, Harris, Spitzer & Williams, 2002). Diagnostic, criterion and construct validity were found to be adequate.

Secondary measures

- Participants will be asked to provide some demographic information, including age, gender, ethnicity
- GAD-A
- Questions related to the participants level of activity pre and post-intervention.

4.4. Recruitment, study procedures and data collection

Participant recruitment process

- A promotion and recruitment pack will include: (1) a poster and (2) a promotional video. These promotional materials will be disseminated to CAMHS staff, School Champions, School nurses, local GP surgeries and the sports clubs themselves.
- Patients will be identified from CAMHS waiting lists and will be invited if they meet the inclusion criteria and will be receive treatment via CAMHS for the 12 week duration of the study. Other sites will not identify participants, they will just advertise the trial using the provided materials.
- The team will also organise attendance at relevant NHS/school team meetings conducted remotely (e.g., using MS Teams) to promote the study. The PI may attend one or more of these promotional meetings, but may also delegate attendance to other members of the research team.
- The team will also organise education sessions for parents/guardians who will be consenting for some of the participants, to give them the opportunity to ask questions
- The promotion and recruitment period will last up to four weeks. Promotion activities will commence in March 2021, prior to obtaining ethical approvals. The formal electronic consent process (described below) will be activated once ethical approval is in place. Potential participants will have the opportunity to contact the research team via email to clarify questions, if necessary. The research team will also hold scheduled video-link sessions, which potential participants can attend to ask any questions they may have prior to the deadline for formal consent.
- Promotional materials described above will contain a weblink to an electronic participant information sheet and consent form (when ethical approval has been given). This method will ensure that no paper copies can be lost or misplaced in the post, and will be an efficient way to gather informed consent using an industry-standard and secure online survey system. A sample text for the consent form that will be available electronically is provided in the Appendix. The promotional material will clearly indicate the deadline for application to participate.
- For those participants under 16 – a parent/guardian will have to provide consent before the adolescent can participate
- For those participants aged 16-18 – they can provide their own consent if they are deemed to have mental capacity. An information sheet will be provided for their parents to ensure they are aware of participation and what is required.
- Consenting participants will be randomly allocated to the online intervention groups, within their regional area. Allocation will be carried out by a researcher who is independent of the research team, using a computerized randomization schedule. Randomisation will be communicated directly to study participants via email within one week of receipt of their electronic consent form.
- The consent and demographic questionnaires will ask for the participants personal email address. This is to ensure we are able to contact the participants throughout the study period (e.g., sending email reminders). Once they have completed the consent form we will email the participants a unique participant pseudonyms, which cannot personally identify any of the study participants. The participant will then use this pseudonym to identify themselves throughout the rest of the study (i.e., to log in to the online session to ensure anonymity is protected when completing the sessions, and as their identifier when they complete the rest of the measures throughout the study). The Grounded Research team will keep a record of the participants email address and associated pseudonym, so if the participant forgets their code they can contact us. The participants email address will then be deleted when the study has completed.
- The measures will be collected by the research team using a secure, web-based, industry-standard data collection system. Therefore, all data collection will be in electronic form, using unique participant pseudonyms, which cannot personally identify any of the study participants. Participants will receive email reminders (sent confidentially by the research team) at the relevant measurement points (see Figure 1) prompting them to access the survey via the Qualtrics.
- Consenting participants will be made aware that this is not a CAMHS referral, and if CAMHS input is required they will need to access the support through the usual route.

Organisation of the online intervention workshops

- Participants will access one of the two interventions described above; using NHS-approved video conferencing software.
- The sessions will be held after school hours.
- We expect that those who agree to take part in the trial complete one session for each of the six consecutive weeks, depending on whether participants are allocated to Group 1 or Group 2.

Data collection and safeguarding procedures

- All participants will be asked to complete the demographic, primary and secondary measures described above at a baseline assessment time-point (week "0" depicted in Figure 1 above). Participants will then be asked to complete a short version of this electronic questionnaire at subsequent measurement time-points depicted in Figure 1.
- The measures will be collected by the research team using a secure, web-based, industry-standard data collection system. Therefore, all data collection will be in electronic form, using unique participant pseudonyms, which cannot personally identify any of the study participants. Participants will receive email reminders (sent confidentially by the research team) at the relevant measurement points (see Figure 1) prompting them to access the survey.
- The final study dataset will be stored in a secure University network drive, only accessible to members of the research team, which is located behind The University of Sheffield Firewall. This will ensure the security and adequate storage of research data, consistent with NHS and academic codes of information governance and data protection.
- All analyses will be carried out at a University site, and data will be held in a restricted-access drive. The study dataset will be held at the University for a minimum of 5 years after the conclusion of the study.

Incentives for participation

- The participants will have the experience of being trained by sports development coaches from local sports clubs when they undertake the physical activity sessions
- The participants will have access to low level psychological interventions without referral into CAMHS, or the associated waiting times
- Participants will be provided with a certificate of achievement if they attend at least four sessions
- Participants will be eligible to be included in two prize draws for Amazon shopping vouchers.
- The first prize draw will take place at the end of the 6-week intervention phase for each group (week 12 in Figure 1). To be eligible for inclusion in this prize draw, participants should have attended at least four intervention sessions and have completed the three online surveys up to that point. The prize will be a £20 Amazon voucher, and there will be one prize per participating site (trial site).
- The second prize draw will take place at the end of the 6-month observational phase (week 36 in Figure 1). To be eligible for inclusion in this prize draw, participants should have attended at least four intervention sessions and have completed all four online surveys. The prize will be a £50 Amazon voucher, and there will be one prize per participating site (trial site).
- In accordance with the University of Sheffield's policy for the ethical use of incentives in research, the prize winners will receive their electronic voucher code via email and they will be asked to return a signed receipt via email, which includes their name and work address, which is essential for auditing purposes and for legal reasons.

5. Statistical analysis plan

5.1. Sample size calculation

A sample size calculation was performed using the method described by Cohen (1992). There is no precedent for this type of trial in this setting, so it is not known whether exposure to the Home Goals intervention may be associated with small, moderate or large effects on measures of depression, anxiety and physical activity. We have therefore followed conventional sample size calculation methods described by Cohen (1992), expecting a moderate effect size as a conservative assumption. In order to detect a moderate effect size using between-groups ANOVA, with 80% power, and an alpha level of 0.05, we estimate that at least 67 participants are needed per group. This would yield a sample size of 134. Expecting a 30% dropout rate, which is common in studies of psychological interventions, we would need to inflate the recruitment target to 192. If we recruit more than the 192, we will accept the young people onto the trial, but we will not collect or analyse their data.

5.2. Primary analysis

Trial data will be summarised using a CONSORT diagram and all analyses will be based on *intention-to-treat* principles. Missing data will be imputed using an expectation-maximization algorithm (Schafer & Olsden, 1998), prior to conducting formal analyses.

The primary hypothesis test (A) will be based on comparing mean outcome measures between groups at week 8, as shown in Figure 1. Mean PHQ-A scores will be compared between groups using analysis of covariance (ANCOVA), controlling for baseline severity.

Sensitivity analyses will be performed to assess the robustness of the main findings. This will involve repeating the above analysis including a random intercept for each trial site and additionally introducing "role" as a covariate (admin; mental health; other clinical role) and any other baseline demographics that may be unbalanced between groups.

5.3. Secondary analyses

ANCOVA (and sensitivity analyses) described above will be repeated at each of the time-points illustrated in Figure 1 (weeks 0, 6, 12, 36), using the PHQ-A, and using the GAD-A as an outcome, controlling for baseline scores. Outcomes at 6-months follow-up (pooled for both groups) will be compared to outcomes at the baseline assessment, using paired-samples t-tests (or an appropriate non-parametric test depending on the distribution of the data).

These analyses will be repeated at each of the post-intervention time-points illustrated in Figure 1 (weeks 6, 36), using the WEMWBS sub-domain scores. These between and within-group comparisons will also be summarised using effect sizes (Cohen's *d*).

Post-intervention measures (weeks 6, 36) will be compared to baseline measures (week 0) within each group, using paired-samples t-tests or an appropriate non-parametric test depending on the distribution of the data. Within-sample pre-post treatment effect sizes will also be computed using the method proposed by Minami et al. (2008).

We will carry out an exploratory analysis of knowledge and levels of activity before and after the intervention.

5.4. Exploratory analyses of mechanisms of change

Change scores will be computed denoting changes in theoretical mechanisms measured using the questionnaires listed in pg. 7. These change scores will be computed between time-point 0 and time-points 6, and 12, denoting changes within the intervention phase.

Residualized change scores across multiple theoretical mechanisms will be entered into a Bayesian network analysis carried out separately for each intervention group, using the post-treatment (weeks 6, 12) PHQ-A as the dependent variable. Each Bayesian network will be trained using a Tree-Augmented Naïve Bayes (TAN) algorithm with adjustment for small cell counts (Friedman, Geiger, & Goldszmidt, 1997). This method offers a data-driven way to model a network of relationships (called *attribute dependencies*) between predictors and their joint influence over a target outcome (post-

treatment OLBI). TAN produces a simple and parsimonious network model where each predictor is allowed to depend on one additional predictor, thus modelling multiple two-way interactions. Variable selection will be performed using a 10-fold cross-validation procedure (Rodriguez, Perez, & Lozano, 2010). The resulting treatment-specific network models will be visualised using directed acyclic graphs (Shrier & Platt, 2008), which enable an intuitive interpretation of key mechanisms of change, their relative importance, and their interrelationships.

6. Ethical considerations

6.1. Considerations about informed consent

This study requires NHS research ethics approval and it will require Health Research Authority (HRA) approval.

In order to obtain informed consent from participants and their guardians in line with good practice guidelines, we will take the following steps:

- Potential participants and their parent/guardian will be invited to contact a member of the research team if they have any further thoughts or questions after meetings and/or reading of the information leaflets. Contact details will be provided as part of the promotional materials described above.
- Potential participants and their parent/guardian will be advised of their right to withdraw from the study at any stage and the right to request their data to be deleted from the study dataset. This will be explicit in the electronic participant information sheet, in the consent form, and will be explained to participants following notification of randomisation. Each participant will receive an electronic copy of the information sheet and consent form via email, for their records.
- For those participants aged under 16 – a parent/guardian will have to provide consent before the adolescent can participate
- For those participants aged 16-18 – they can provide their own consent if they are deemed to have mental capacity. An information sheet will be provided for their parent/guardian to ensure they are aware of participation and what is required.

We will also be collecting fully anonymous data described above. We consider that our proposed method for aggregating and analysing fully anonymized data is congruent with the NHS information governance policy and good practice guidelines.

6.2. Potential for distress

Given the psychoeducational nature of the interventions, we do not envisage any potential for significant distress or adverse events. Nevertheless, participants will receive the contact details for the chief investigator in the information sheet, if they should wish to make a complaint or to raise any concerns about the intervention or conduct of the study. In the rare event that a participant should become distressed, they will be provided information by the research team about usual sources of psychological and or occupational health support available to employees in their NHS Trust.

Participants and their parent/guardian will also be provided with an information sheet listing support services that are available to them should any issues arise.

Participants will be made aware that if the research and/or delivery team become concerned about the welfare of a participant, or any abuse of the participants or someone else is disclosed we will have to break confidentiality. We will discuss this with the participant, but we may break confidentiality without their approval if we feel it is appropriate. Confidentiality will be broken by either referral to the GP or

emergency services depending on the severity and urgency, parents/guardians will also need to be informed.

7. Risk management

7.1. Risks to participants

See above section.

7.2. Risks to research team

See above section.

7.3. Potential for disclosure

See above section.

8. Dissemination

After the conclusion of data analysis, we plan to disseminate findings about this study using a variety of forms of communication, including:

- Scientific journal publications
- Newsletter in lay terminology
- NHS Trust communications newsletter and email
- NHS Trust conferences, strategic meetings
- Mental health conferences in the UK and abroad

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