THE STANDING UP FOR MYSELF (STORM) PSYCHOSOCIAL GROUP INTERVENTION FOR YOUNG PEOPLE AND ADULTS WITH INTELLECTUAL DISABILITIES: ADAPTATION FOR DIGITAL DELIVERY AND PILOT

Sponsor:	**University College London (UCL)**
Funder:	**Public Health Research (PHR), National Institute for Health Research (NIHR)**
Funder ref:	**17/149/03**
REC ref:	**UCL Research Ethics 0241/005**
ISRCTN ref:	**16056848**
Internal reference	**0241/005**
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This study is funded by the National Institute for Health Research (NIHR) Public Health Research programme (NIHR PHR Project 17/149/03). The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.

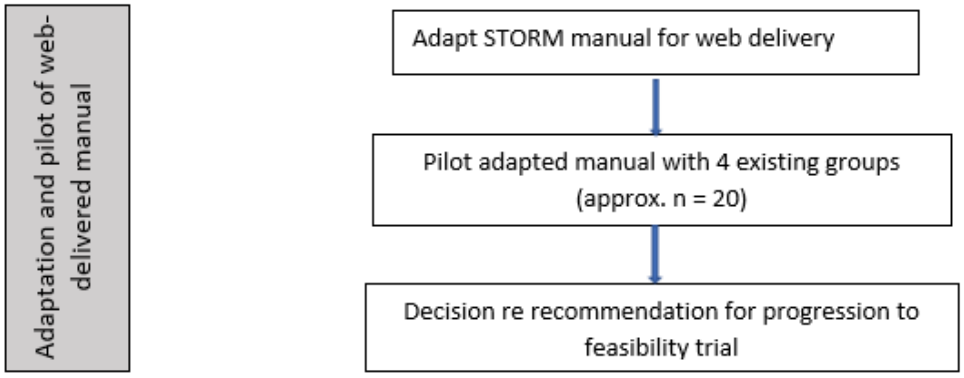
1 Synopsis of proposed amendment to study design for adaptation and pilot phase

Development phase	Adaptation of the STORM intervention for digital delivery and piloting
Study participants	Young people and adults with mild to moderate intellectual disabilities
Planned sample size	4 groups (approx. N=20) to pilot adapted remote delivered version.
Inclusion criteria	Groups that wish to take part in the study will: • Be in place already (although group meetings may have been disrupted due to Covid-19 and associated social restrictions); • Intend to continue or restart meeting as a group for at least 3 further months; • Have at least 3 and no more than 8 members with ID who wish to participate in the intervention; • Be willing to replace 5 of their usual meetings with STORM; • Have a group facilitator willing to receive training and facilitate the STORM intervention and protocol in either face-to-face or digital form; • Organisational support to deliver the study intervention. Individual participants will be: • aged 16+ years; • have an ID as defined by an administrative definition; • a member of an established group for people with ID (educational, activity, social or self-advocacy focused); • able to complete the outcome measures (with or without support) and engage with the STORM intervention; • have access to the internet and a device that can access web meetings, be this via Zoom, Skype, Microsoft Teams or Google Meet; • where needed, have support to access web based meetings; • have capacity to provide informed consent to participation in the study. • Able to communicate in English
Exclusion criteria	Groups will be excluded if: • they are run as part of NHS services; • some of their regular members decline taking part in STORM-e and it is not possible to find alternative meeting times to run STORM-e. Participants will be excluded from the research if they do not meet any of the inclusion criteria or do not provide consent.
Intervention	STORM-e: web delivered adaptation of STORM, consisting of 4 weekly 90-minute sessions and a 90-minute follow-up session (delivered around four weeks after session 4).
Primary objective of adaptation phase	To carefully adapt the STORM intervention to a web delivered version and pilot this to assess whether it is practical to deliver this version to established groups of people with ID in a range of community, social and educational settings. The findings will be used to inform the decision whether a subsequent feasibility trial is indicated (which may be a 3-arm trial of both versions of STORM, a 2 arm trial of one STORM version, or potentially no trial).

Secondary objectives of adaptation phase	To assess the feasibility of collecting all planned outcome data digitally. To characterise 'Usual Practice' in a changed service delivery context.
Primary outcomes of adaptation phase	Adaptation phase: Acceptability of delivering STORM to groups in web delivered format
Secondary outcomes of adaptation phase	Adaptation phase: Feasibility of remotely collecting outcome and process data. Description of 'Usual practice' in a changed service delivery context.
Planned study period	Revised design to include 8 months for adaptation to STORM-e and piloting. 3 months for analysis and reporting.

2 Revised study summary & schema

2.1 Participant flow diagram



3 Background

The Covid-19 pandemic and associated social restrictions have changed the way in which services and support are delivered, including to people with intellectual disabilities (ID). In response to lockdown and the need for distancing, services have largely suspended face-to-face (F2F) meetings and, wherever possible, have shifted to supporting their members through virtual methods, in particular web-based video meetings and WhatsApp calls. Our partner organisations and other third sector organisations that we have consulted inform us that this shift has been (surprisingly) successful for people with mild to moderate ID, many of whom, with initial support, have learnt how to use virtual meeting software/apps. In view of the fact that many individuals with ID have underlying health conditions that place them at increased risk to Covid-19, many organisations anticipate that they may continue to use virtual methods for the foreseeable future to engage with people with mild to moderate ID, and as part of a more diverse offer once they are able to resume F2F meetings. The wide spread move towards much greater use of digital technologies by people with ID through force of circumstance offers an opportunity to assess the use and value of digital methods to promote well-being in this population, a priority in current health policy yet an area where people with ID have been largely excluded.

The rise of digital interventions

The use of digital health (also known as e-health) interventions has grown rapidly over the last decade, a development that has accelerated in the wake of the Covid-19 pandemic. Evidence supporting the acceptability of digital mental health individual interventions among the general child and adult population has been generated in a range of settings (e.g., Deady, Choi, Calvo, Glozier, Christense & Harvey, 2017; Newby, Twomey, Li & Andrews, 2016). A meta-analysis of five studies involving a total of 429 participants by Andersson et al. (2015) compared F2F and individual e-CBT for depression. The results favoured guided e-CBT, with the small observed difference of no clinical significance though. A more recent meta-analysis of 17 studies found individual e-CBT to be more effective than F2F CBT at reducing depressive symptomatology, with no differences between the two interventions on participant satisfaction (Luo et al., 2020). Overall, digital interventions targeting individuals show promising outcomes when compared to face-to-face delivered interventions. Positive results have also been reported for group interventions. In a randomised controlled trial by Wagner et al. (2013), depressed adults were randomly allocated to internet-based or F2F 8-week cognitive-behavioural group therapy, with both arms receiving the same treatment modules in the same chronological order and time-frame. While both delivery formats showed large reductions in depression, 3-month after the end of treatment, results in the online group remained stable yet participants in the F2F group showed significantly worsened depressive symptoms.

The use of e-health interventions with people with ID has been very limited though and this population has generally been excluded from e-health research (Vereenooghe, Gega & Langdon, 2017). As Sheehan and Hassiotis (2017) note, even though the scope of digital mental health is vast and people with ID who face multiple threats to their mental well-being could benefit, they seem to have been relatively neglected in the discourse around digital mental health and the development and implementation of new (digital) interventions. One reason for this is generally the lower levels of

access to the internet among this population, what has been termed the 'digital divide' (Lussier-Desrochers et al., 2017). In 2015, Ofcom reported that only 73% of people with ID in the UK had access to the internet compared with 88% of people with no disabilities, some of this difference was explained by the lower levels of access to PCs/ laptops and smartphones reported for people with ID (68% vs. 79% of people with no disabilities). In 2020, this 'digital divide' continues, with evidence suggesting that people with ID when compared with other disability groups have the least access to digital devices and report the highest difficulty when using the internet (Johansson, Gulliksen & Gustavsson, 2020). Contextual barriers to the use of digital interventions with people with ID also include providers' concerns about their own lack of digital skills which limit their opportunity to support people with ID (Oudshoorn et al., 2020). However, it has been argued that such barriers can be overcome with appropriate support and adaptations and a small, but growing, literature attests to the value of digital technologies to improve health as well as educational, vocational and leisure opportunities for people with ID (Sheehan & Hassiotis, 2017). Anecdotally, since the start of the Covid pandemic across many services supporting people with ID, there have been significant efforts to support access to IT to ensure support can be delivered remotely.

The rationale for a digital version of the STORM intervention

That the digital divide needs tackling if we are to avoid increasing existing health inequities has never been more evident than in the wake of the pandemic. Increasing access to digital technology and the internet and generating e-health interventions that can improve the well-being of large numbers of people with ID should be a priority and is in line with the need to challenge health inequalities in the UK health and social care system stipulated in the NICE Evidence Standards Framework for Digital Health Technologies (2019).

Having the option to meet virtually can promote self-determination and social participation for people with ID (Ayres, Mechling & Sansoti, 2013), with benefits including increased communication and social interaction (Reichenberg, 2016). An exploratory study by Vereenooghe et al. (2017) showed that digital technology could be a means to widen access for people with ID to therapy. The potential benefits of digital interventions for people with ID are also supported through feedback we have received during our consultations with self-advocates with ID and third sector organisations for people with ID, conducted at various time points since lockdown. The feedback indicates that for some, virtual meetings are a preferred means of connecting with others as home is a safe and familiar space to discuss personal experiences, and can allow them to feel more confident to speak up and engage in discussions. Many people with ID experience anxiety about moving around their local community or travelling alone, or are reliant on support from others to attend services, both of which can act as barriers to joining and attending F2F groups. Virtual meetings have been suggested to help overcome this, with some organisations reaching more of their members since having to replace F2F with virtual meetings. Furthermore, people with ID living in rural areas of the UK are often prevented from using community services and joining groups due to the absence or inaccessibility of public transport and/or support required to travel. Organisations we have consulted, particularly those that cover rural areas, have informed us that attendance at F2F meetings is lower among their members during the winter months and greater use of digital meetings could fill an important gap.

The immediate need for and importance of STORM to help people with ID to discuss negative experiences with their peers and resist stigma has been highlighted during the Covid-19 pandemic. Discrimination and inequalities people with ID have experienced during this time have been highlighted by many (e.g. Lodge, 2020; Thomas, 2020). Self-advocacy groups have discussed feeling neglected by the government whilst their members have had to shield, and have complained about lack of reasonable adjustments to communicate Covid-19 rules and discriminatory resuscitation notices. By continuing to meet virtually, these organisations have provided their members with space to connect with others and reduce the negative consequences of social isolation. They have emphasised their need for a space to discuss their negative experiences and stigma they face more generally, particularly at this time when they feel discrimination and social inequalities have been heightened. Hence our PPI advisors are firmly opposed to an extended pause to the STORM study until services for people with ID can resume F2F provision.

Given current barriers to groups meeting F2F, adapting STORM so that it is suitable for digital delivery and, in future, being able to offer alternative versions of STORM will allow more groups of people with ID to access STORM, in line with the long-term goal to offer STORM as a widely and freely accessible public health intervention that can enhance the ability of people with ID to manage and resist the stigma they often face in their everyday lives. Our extensive PPI work has generated evidence in line with NICE's (2019) framework for digital health technologies, including an indication that a digital version of STORM is viewed as credible by its intended future users and experts in the field, and highly relevant if its implementation were successful. By potentially extending the reach of STORM, an intervention that challenges discrimination and promotes equality, within the ID population through creation of a digital version we seek to challenge exclusion and promote equality at multiple levels.

4 Proposed adaptation of the original STORM intervention for digital delivery

In view of the aforementioned issues, we propose to carefully adapt the STORM intervention for digital delivery (STORM-e) to people with mild to moderate ID. In doing so we will work closely with our PPI partners and intended users of STORM-e, and model delivery of the adapted intervention and outcome measurement in a virtual environment through a small pilot with four groups. We will also work with a new partner *Unthinkable Digital*, experts on digital inclusion and learning design, to ensure that the adapted digital version is optimised for engagement of people with ID and delivery by facilitators who may well be new to online facilitation of groups.

If the initial pilot indicates that STORM-e is practical and acceptable, we will make essential revisions to STORM-e identified during the pilot and seek funding for a subsequent feasibility study. Whether this should be a 3-arm trial of STORM and STORM-e versus Usual Practice (UP), or a 2-arm trial of only the e- or F2F version of STORM versus UP will be determined by the SMG and SSC following the adaptation and piloting work.

Aims

1. To adapt and pilot the existing STORM intervention for online delivery (STORM-e), ensuring that the content, number of sessions and direct contact time are the same for both STORM and STORM-e.
2. To investigate the feasibility and acceptability of STORM-e, when delivered to groups of people with ID online.
3. To test digital administration of the study outcome measures.
4. To build on our community assessments to describe what UP may look like for groups of people with mild to moderate ID in the wake of Covid-19, to inform a potential future feasibility trial.

Furthermore, we will review and revise the Process Evaluation during the adaptation phase to ensure the proposed methods are fit for purpose for a future potential feasiblity trial involving STORM-e.

4.1 Phase 1 Intervention adaptation and piloting

4.1.1 Phase 1a Intervention adaptation (months 1-4)

We will establish an Intervention Adaptation Group (IAG) which will oversee the adaptation and report back to the SMG and SSC at the end of the STORM-e pilot. The IAG will consist of representatives of our PPI advisors (group facilitators and people with ID), the independent co-chair of the PPI group, Mencap as our intervention delivery partner, digital inclusion experts, and members of the research team.

The work of this group will build on community assessments already conducted by the research team via interviews with key informants and stakeholders to identify key considerations in adapting the STORM intervention for digital delivery. We have explored the experiences of third sector organisations of shifting to remote engagement with their members, their learning regarding what works in web-delivering activities, how to manage risks to privacy, and their ideas for maximising engagement when virtually delivering a group intervention like STORM. We will build on the insights generated to date through a web survey, disseminated with support from our partner organisations, to understand what they have learnt regarding what works in making the shift from F2F delivery to web-delivered activities, including how to prepare and support access to web based meetings and engagement in them, manage privacy concerns, and what Usual Practice looks like in the wake of the pandemic and associated social restrictions.

The focus of this work will be on how to maximise access to and engagement with STORM-e to ensure it is inclusive and to address potential barriers to access to and/or engagement with the intervention arising from multiple sources, including:

- access to and familiarity with technology to be used in delivering STORM-e;
- demands on group facilitators tasked with delivering STORM-e;
- changes to group dynamics and interactions when moving from a F2F to a virtual environment;
- the role of carers/family members in supporting participants to engage with the intervention and outcome assessments;
- challenges to participants' right for privacy.

The adaptation will review the following aspects of the STORM intervention and make adaptations where necessary:

- structure
- content
- delivery mechanisms
- participant needs for support

The work to be overseen by the IAG will be carried out by the UCL based research team in months 1-4 of the adaptation and piloting phase, as outlined below.

4.1.1.2 *Adaptation programme of work*

Month 1

IAG Meeting 1- Preparatory meeting

- Explain plans for adapting STORM from face to face to online delivery (STORM-e)
- Discuss role of the group- what the work will look like and how we will work together
- Set out timetable of activities, identify if any gaps or additional activities needed

Preparatory activities and follow-up

- Research team to bring summary of results from consultation with organisations that have been running online groups for people with learning disabilities, including challenges they faced and how these were overcome.
- IAG members and research team to relate first hand experiences of people with ID about their experience of online groups and what the team will need to think about, e.g. things that have helped them.
- Focus groups with individuals with ID, co-led by our self-advocate expert advisors, regarding their experiences of moving to meeting their peers on-line.
- A web survey using Qualtrics, disseminated via our partner organisations, to understand what they have learnt regarding what works in web-delivering activities, and making the shift from face to face delivery, and what UP looks like.
- Draw on evidence and guidance on engaging people with ID in digital meetings and interventions and using video conferencing platforms including grey and published papers about experiences during the current pandemic.
- Schedule all planned IAG meetings and share with members
- Prepare structure and materials to share for next meeting.

Arrange for all members of the IAG to have opportunity to review the existing STORM manual and materials and sample what digital delivery might look like.

Month 2

IAG Meeting 2- Structure, content and participant support

- Discuss key changes needed to adapt STORM manual for digital delivery in terms of structure and content (with focus on key aspects: 90 minute sessions, interspersing of videos, guided group discussions and activities).
- Discuss feedback from consultation work completed and implications for participant needs for support in accessing STORM-e and maintaining engagement in sessions.
- Discuss participants' rights to privacy and confidentiality and strategies for mitigating risks to these in relation to support offered for participating in STORM-e.

Preparatory activities and follow-up

- Produce summary of IAG work to date on structure, content and participant support needs
- Research team to work on adaptations to structure and content of STORM manual and materials agreed by IAG.
- Research team to consider with Mencap as intervention partner implications of shift to STORM-e for facilitator training and supervision, to identify and update associated materials.
- Research team to start to identify which groups might be able to take part in a pilot of STORM-e-screening and availability for training.

Months 2-3

IAG Meeting 3- Workshop on optimising STORM-e for online delivery

- Review adaptations made by the research team to structure and content of STORM manual and materials and identify any additional adaptations to be made.
- Summarise and discuss how to manage additional demands placed on group facilitators tasked with delivering STORM-e (identified during preparatory work, see above).

Follow up and preparatory activities-

- Research team to finalise online delivery methods.
- Finalise facilitator training and supervision arrangements with intervention delivery partner.

Review process evaluation materials and revise in line with STORM-e delivery methods.

Months 3-4

IAG Meeting 4- Finalising of materials for pilot of STORM-e and process evaluation

- Present final STORM-e manual to the group for approval
- Present plans for ensuring demands on facilitators delivering STORM-e are well managed through training and supervision arrangements finalised with intervention partner
- Present key proposed revisions to process evaluation

Follow up

Research team to make final revisions ahead of pilot

4.1.2 Other activities during months 1-4

Concurrently with adaptation of the manual, during months 1-4 the research team will also:

(a) seek to characterise Usual Practice (UP). This will be achieved through an online survey of existing third sector organisations across the UK. Our survey will include questions about what discussion/conversation based group meetings are delivered, by whom, mode of delivery, location, and where UP has been modified in response to Covid-19, what changes have been made and how well they have worked. This survey will be delivered using Qualtrics and disseminated via our existing contacts, social media channels, and our partner organisations Mencap, the Foundation for People with Learning Disabilities and People First Dorset. We will also complete desk research on published and grey literature on virtual group support for people with ID during the current pandemic.
(b) test digital delivery of the outcome measures at baseline. All procedures for supporting remote administration of study measures will be finalised as part of this adaptation phase. We will also draw on the experience of the first wave of data collection in a current UKRI/NIHR funded Covid-19 study of people with ID (research team members Jahoda, Hastings and Scior are project members). Any queries or difficulties will be resolved in collaboration with the self-advocate PPI advisers who have already provided input on the plans for outcome measurement during the earlier stages of this project. Digital administration of the outcome measures to all STORM-e pilot participants, along with evidence from parallel research studies, will inform the team whether it is feasible to collect outcome data for a feasibility trial using digital methods. If successful, this will mean we can re-consider our sampling procedures and expand the geographical regions we can recruit from for the feasibility trial.

4.1.3 Phase 1b Pilot of STORM-e (months 5-8)

In phase 1b, the adapted intervention will be piloted with four groups (approximate N = 20), giving priority to groups that already expressed interest in participating in the STORM study. The average anticipated pilot group size of n=5 arises from feedback received during our stakeholder consultations that smaller group sizes work better in web meetings. This group size is also likely to mirror smaller group sizes we would be likely to encounter in any future feasibility study comparing F2F STORM with STORM-e, due to social restrictions that may affect work for some time to come. Of the four pilot groups, at least one will need to do some additional work to allow all its group members to access STORM-e, in order to allow us to explore 'live' how issues around access to technology, support, and provisions to ensure privacy are managed.

Following facilitator training, all STORM-e sessions will be recorded locally in line with data protection regulations. The recordings will be used alongside STORM-e facilitator records and notes kept in supervision to identify what challenges to implementing STORM-e as planned arose and how these were managed. The insights gained will help us identify the need for further revisions to the manual and/or delivery mechanisms ahead of a feasibility study.

To understand implementation of STORM-e, we will monitor what proportion of pilot participants needed help to access the digital intervention and what this help consisted of. For those participants who received support to access STORM-e, we will monitor how participant privacy is assured, whether

threats to privacy arise, what their impact is on participant engagement, and whether following the manual allows STORM-e facilitators to manage these or whether additional guidance is needed. These issues will be assessed via facilitator notes, session recordings and interviews with participants and facilitators.

We will ask group facilitators to record group members' attendance at each session and occasions when group members experienced access and/or internet connection problems. Facilitators will also be asked to note down after each session challenges to delivering the intervention as intended and to participant engagement and to bring these notes for discussion in supervision. Feedback on how they addressed challenges and the impact will be elicited in supervision and shared with the research team. Additionally, we will use the session recordings to triangulate facilitators' records and assess what proportion of the sessions participants were able to attend (to account for participants dropping out at any point, either due to poor internet connection or for other reasons).

At the end of the last STORM-e session of each pilot group, our PPI advisors will act as peer researchers and co-lead a group discussion to obtain participants' views on STORM-e, what went well and what got in the way of their taking part and potentially benefitting from the intervention. They will explore whether ethical risks, including instances where individual participants needed practical or emotional support and risks to privacy during sessions, were managed in an acceptable manner. Post-intervention outcome measures will be completed with all pilot participants as soon as is feasible after the last STORM-e session.

A researcher will interview each pilot group facilitator about their experiences of delivering STORM-e. Interview data will be combined with supervision notes kept by the Mencap intervention lead to assess barriers and facilitators to STORM-e implementation.

During the pilot we will also test our revised plans for the process evaluation of STORM-e. This will include assessing the feasibility of recording of STORM-e sessions by facilitators locally and sharing of recordings with the research team to ensure compliance with data protection regulations. We will assess whether these recordings can be used to assess adherence and attrition or whether facilitator records need to be combined with review of session recordings to achieve this.

The outputs from Phase 1b will be:
(a) an adapted intervention manual for delivery of STORM-e that can be tested within a feasibility study;
(b) a revised logic model that incorporates what we have learnt during the pilot about mode of delivery and contextual factors;
(c) a description of UP across third sector organisations in the wake of the Covid-19 pandemic;
(d) a revised outcome assessment protocol suitable for virtual delivery for use within a feasibility study, and
(e) data regarding the feasibility of collecting outcome data remotely.

4.1.4 Phase 1c Decision phase

During the adaptation work, the SMG and SSC will meet at regular intervals to monitor progress of the work, focusing on these milestones:

Month 4: Successful recruitment of groups for pilot

Month 5: Completion of manual adaptation

Month 8: Completion of pilot

During month 8, the SMG will meet to review the progress and preliminary findings from the STORM-e pilot. In particular, it will consider key indicators of successful adaptation, and also whether the original F2F version of STORM is feasible at that point in time. If both the online and F2F versions of STORM appear feasible, they will consider what questions need to be addressed about the design of a potential future definitive RCT and may recommend seeking funding for a feasibility study. In case STORM-e was shown to be feasible but the original F2F version of STORM was still not feasible, the SMG may conclude that a 2-arm study of STORM-e versus UP is indicated. In case STORM-e emerged as not feasible for some reason during the adaptation work and piloting but the original F2F version was feasible, the original 2-arm study of STORM versus UP could be pursued.

During month 9, the SSC will be convened to consider the outputs and SMG's recommendations. Using the indicators of successful adaptation outlined below they will make a recommendation to the NIHR PHR programme whether a funding application for progression to a feasibility trial is justified, and if so what design and interventions are to be employed.

1. Feasibility of delivery of STORM-e - STORM-e pilot facilitators' records and feedback, supervision notes, and review of session recordings demonstrate:		
Poor indicator for progression	Indicator for progression, with further adaptations needed	Strong indicator for progression
- attendance was poor (participants on average attended less than 3 sessions and within session presence and engagement was poor, unlikely to be resolved with adaptations - technical problems were significant, were not resolvable and likely to severely impair future implementation - would not recommend STORM-e to others nor consider running it with other groups	- good attendance across sessions (participants on average attended at least 3 sessions), BUT, presence and engagement within sessions was somewhat impaired by technical issues. These would be resolvable with some additional modifications/guidance. - would only consider recommending STORM-e to others or running another group if specific changes were made to the content, structure or	- good attendance across sessions (participants on average attended at least 3 sessions) and presence and engagement within sessions was good, any technical problems were resolvable and did not unduly impact on running the session or engagement - would recommend STORM-e to others and consider running it with another group - felt able to monitor participants' emotional

- felt unable to monitor participants' emotional responses during sessions and to respond accordingly, modifications unlikely to resolve this. - privacy threats were evident and unmanageable or significantly impacted on engagement and participation. Further modifications unlikely to adequately resolve this.	accessibility of the technology. - felt modifications were needed to monitor participants' emotional responses during sessions and to respond accordingly, but these would be straightforward to implement through additional guidance or adaptations. - privacy could be better managed with some modifications	responses during sessions and to respond accordingly - able to manage any threats to privacy for group members either by following the manual or taking additional steps
2. Acceptability of STORM-e - Feedback from STORM-e pilot participants indicates:		
Poor indicator for progression	Indicator for progression, with further adaptations needed	Strong indicator for progression
- a majority of participants judged the digital delivery method of STORM-e as not acceptable and would not recommend STORM-e to others. Changes unlikely to remedy this. - on occasion when participants may have found intervention contents distressing, they either felt un-supported by the group facilitator and/or their peers, or were un-able to access support outside of the group. Changes unlikely to remedy this. - participant privacy was not maintained in a way that allowed them to fully engage in the sessions. Changes unlikely to remedy this.	- less than half judged the digital delivery method of STORM-e as acceptable and would recommend STORM-e to others without changes. - on occasion when participants may have found the intervention contents distressing, they did not always feel well supported by the group facilitator and/or their peers, or were not always able to access support outside of the group when they needed it. Changes would mean that support in this area could be improved. - participant privacy was mostly maintained but there were occasions when threats to privacy affected engagement and/or raised concern. Changes in this area could	- a majority of participants judged the digital delivery method of STORM-e as acceptable and would recommend STORM-e to others. - on occasion when participants may have found the intervention contents distressing, they either felt well supported by the group facilitator and/or their peers, or were able to access support outside of the group - participant privacy was maintained in a way that allowed full engagement in the sessions.

	make this more acceptable in the future.	

The risk of exclusion from STORM-e due to technical issues will be considered in relation to a target of no participant missing more than two sessions, or parts thereof (other than brief connectivity problems not exceeding 10 to 15 minutes), due to technical problems.

A decision whether it is feasible to collect outcome data remotely will be informed by responses to collection of baseline data during the pilot. Should 80%+ of collected outcome data be usable this will be deemed feasible, if 70%-79% of collected outcome data are usable we will review and revise the procedures for remote data collection. If less than 70% of collected outcome data are usable, we will consider with the SMG and SSC whether there are strategies to improve this (e.g., drawing on data from our UKRI/NIHR Covid-19 study with people with ID) or whether remote collection of data is not feasible.

4.1.5 Timetable

An overview of the timetable for adaptation to STORM-e is provided in Table 1 below. A more detailed timetable is provided in the Gantt chart (version 4, 11.11.2020).

Table 1. Overview of timetable

Nov 2020 – March 2021	Adaptations to STORM-e
March to June 2021	Pilot of STORM-e
June-July 2021	Reporting to SMG, SSC and Decision phase
Sep 2021	Final report to Funder

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