THE STANDING UP FOR MYSELF (STORM) PSYCHOSOCIAL GROUP INTERVENTION FOR YOUNG PEOPLE AND ADULTS WITH INTELLECTUAL DISABILITIES: FEASIBILITY STUDY.

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SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the relevant study regulations, GCP guidelines, and SOPs.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the clinical investigation without the prior written consent of the Sponsor

I also confirm that I will make the findings of the study publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

Chief Investigator		
Name Katrina Scior	**Signature** 	**Date** 18.12.2019

General Information This protocol describes the STORM study, and provides information about the procedures for entering participants into the study. The protocol should not be used as a guide, or as an aide-memoire for the treatment of other participants. Every care has been taken in drafting this protocol; however, corrections or amendments may be necessary. These will be circulated to the known Investigators in the study.

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For **all queries** please contact the STORM team through the main study email address. Any clinical queries will be directed through the Study Manager to either the Chief Investigator or Co-Investigators

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Randomisation
See section 14.1

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Glossary of abbreviations

AE	Adverse Event
CI	Chief Investigator
CRF	Case Report Form
CTR	Centre for Trials Research
CU	Cardiff University
GCP	Good Clinical Practice
GP	General Practitioner
HE	Health Economics
ISF	Investigator Site File
ISRCTN	International Standard Randomised Controlled Trial Number
NHS	National Health Service
PIS	Participant Information Sheet
QA	Quality Assurance
QALY	Quality-adjusted Life Years
QC	Quality control
R&D	Research and Development
RCT	Randomised Controlled Trial
REC	Research Ethics Committee
RGF	Research Governance Framework for Health and Social Care
SAE	Serious Adverse Event
SOP	Standard Operating Procedure
SSA	Site Specific Assessment
TMF	Trial Master File
SMG	Study Management Group
SSC	Study Steering Committee

1 Amendment History

The following amendments and/or administrative changes have been made to this protocol since the implementation of the first approved version.

Amendment No.	Protocol version no.	Date issued	Summary of changes made since previous version

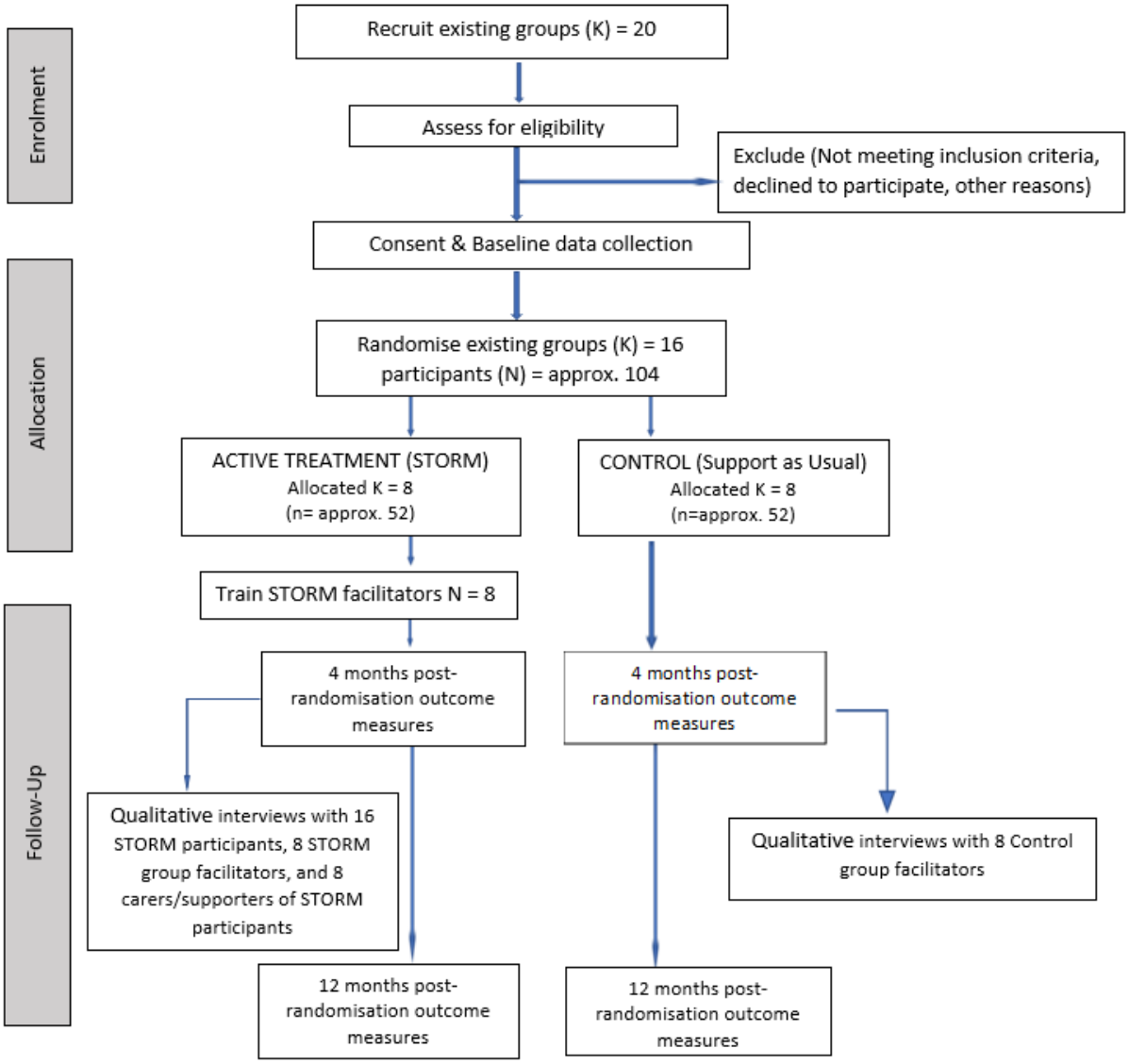
2 Synopsis

Short title	The STanding up fOR Myself (STORM) psychological group intervention for young people and adults with intellectual disabilities: Feasibility study
Acronym	STORM Feasibility study
Internal ref. no.	0241/005
Development phase	Feasibility study
Funder and ref.	NIHR PHR 17/149/03
Study design	2 arm cluster-randomised feasibility study
Study participants	Young people and adults with mild to moderate intellectual disabilities aged 16+
Planned sample size	16 groups (8 to STORM, 8 to comparator) with approximately 104 participants in total (52 per arm)
Inclusion criteria	Groups that wish to take part in the study will: • Be in place already; • Intend to continue meeting as a group for at least 3 further months; • Have at least 4 and no more than 10 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; • Organisational support to deliver the study intervention. Individual participants will be: • aged 16+ years; • have an ID as defined by an administrative definition; • be able to complete the outcome measures (with support) and engage with the STORM intervention; • be a member of an established group for people with ID (educational, activity, social or self-advocacy focused). • have capacity to provide informed consent to participation in the study.
Exclusion criteria	Groups will be excluded if: • they are run as part of NHS services; • some of their regular members decline taking part in both the study and STORM and it is not possible to find alternative meeting times to run STORM. Participants will be excluded from the research if they: • do not have an ID; • are unable to communicate using English; • are younger than 16 years of age;

	• do not have capacity to consent.
Treatment duration	2 months
Follow-up duration	12 months
Planned study period	24 months
Primary objective	To assess the feasibility of delivering STORM successfully to established groups of people with ID in a range of community, social and educational settings
Secondary objectives	To inform the decision on a primary health related outcome for a potential future definitive study
Primary outcomes	Primary feasibility outcome data on recruitment and retention; fidelity and acceptability of intervention delivery
Secondary outcomes	Mental wellbeing, self-esteem, self-efficacy in rejecting prejudice, negative reactions to discrimination, and sense of social power, assessed at baseline, end of intervention (4 months post randomisation), and at 12 months post randomisation.
Intervention	STORM: 4 weekly 90-minute sessions and a 90-minute booster session (delivered around four weeks after session 4).

3 Study summary & schema

3.1 Participant flow diagram



3.2 Study lay summary

Someone is said to have a learning disability (or 'intellectual disability' (ID)) if they have a reduced ability to understand new or complex information and to learn new skills, and a reduced ability to cope independently, which started before adulthood. People with ID are more likely to experience

poor physical and mental health and on average die 15 to 20 years younger than the general population. This is not simply due to their ID or related medical conditions, but in large part to being more likely to experience low incomes, unemployment, poor housing, social isolation and loneliness, bullying and abuse. A recent report concludes that to improve lives and health outcomes for people with ID, more needs to be done to reduce stigma (negative stereotypes, prejudice and discrimination).

Stigma has been linked to lower self-esteem, quality of life, and mental health, including for people with ID. Efforts are being made to reduce ID stigma within society and among specific groups, such as health care providers. However, efforts to empower people with ID themselves to challenge stigma are lacking. We have developed Standing up for Myself (STORM), a new group-based programme to address this gap. STORM is designed for people with mild to moderate ID aged 16+ and seeks to give them the means to challenge stigma in their everyday lives. It consists of four 90-minute group sessions and a booster session and involves a range of activities, including watching films of people with ID talking about their experiences of prejudice and bullying, group discussions, and planning how to stand up to prejudice and discrimination in everyday life. STORM is delivered by staff in charities, colleges and other services that run groups for people with ID. Staff receive training in how to deliver STORM, how to look out for possible signs of distress in STORM participants and support them, and ongoing support (supervision). So far, we have developed STORM and piloted it with ten groups involving 67 people with ID. Feedback from group members and staff who led STORM groups has been very positive and indicates a great need for and interest in this intervention. We found initial positive effects of STORM on group members' self-esteem, mental health and confidence in challenging stigma.

We now need to address further important questions before we will know whether a large research test (a trial) of STORM is called for. We will ask 16 community organisations across South East England who run groups for people with ID to take part in the research. Of the 16, eight will be chosen at random to deliver STORM to one of their groups. The other eight (the “control group”) will not get STORM and will carry on with their usual group meetings. In total, we expect about 104 people with ID will take part in the research. We will examine how easy it is to recruit groups and participants, how many drop out, and how good facilitators are at delivering the sessions as they were trained to. We will also assess whether participants are willing and able to complete all outcome measures and whether STORM appears to improve mental wellbeing, self-esteem and confidence in standing up to

stigma. STORM was developed with close input from people with ID and staff who run groups for people with ID. In the new research, self-advocates with ID and staff from three organisations who have worked on STORM already will be closely involved.

4 Background

ID is characterised by an IQ below 70 and associated deficits in adaptive functioning, arising before the age of 18, and is estimated to affect 1.4% to 2% of the UK population [2]. Adults and young people with ID are at increased risk of mental health problems, with recent prevalence estimates of diagnosable psychiatric disorders at 30% to 50% [3,4]. They face substantial social and health inequalities, at least partly due to stigmatising attitudes within health, social care and education systems, and wider society [1,5]. The increased risk of mental health problems is due to a range of biological, psychological, and environmental factors - one important environmental factor is stigma: negative stereotypes about people with ID, which lead to prejudice and discrimination. Despite positive changes in policies, service provision and societal views, young people and adults with ID still frequently face negative attitudes and discrimination [6]. These in turn render people with ID more vulnerable to a negative sense of self and low self-esteem [1,7,8], poor quality of life [1,5,9], and mental health problems [10,11]. Accordingly, interventions that seek to reduce stigma and that ideally empower people with ID to challenge stigma themselves, such as our new STORM programme, have the potential to improve the wellbeing of people with ID and to reduce inequalities.

Young people and adults with ID often face negative attitudes and interactions arising from their stigmatised status in society, including bullying, harassment, hostility and other negative encounters in the community, as well as discrimination in education, employment, health and social care settings. However, due to social and cognitive skills limitations associated with ID and reduced social support, their capacity to deal with others' negative responses is often diminished. Consistent associations have been reported between stigma and poorer self-reported health outcomes [5], increased anxiety and depression [10,11], and lower self-esteem [7,8] in people with ID. Consequently, ID stigma needs tackling at multiple levels, as articulated in our theoretical framework [12]. Interventions are in place to tackle ID stigma at institutional level and to promote more positive attitudes towards people with ID among the public and among key target groups (e.g. health care providers). Our research reviews concluded that, to date, interventions have not been developed that are effective in reducing the negative effects of stigma on people with ID, or that increase their capacity to manage stigma

[12,13,14]. Psychological and psychosocial approaches that are suitable to this end, such as cognitive behavioural and narrative approaches, have been successfully used in other fields to help buffer individuals against stigma and its negative consequences, including low self-esteem [15,16]. Evidence that empowering "the victim" is effective comes from meta-analyses of interventions with victims of bullying [17,18]. Developing effective ways of enhancing the capacity of people with ID to manage and resist stigma, both individually and collectively, is likely to have positive effects on their self-esteem, mental health, and general well-being. In turn, reducing the negative impact of stigma may reduce demands on (mental) health and social care services as a result of improved well-being (see Logic Model).

'Stigma resistance' has been researched in diverse clinical areas. A recent meta-analysis found strong associations between stigma resistance and self-stigma, self-efficacy, quality of life and recovery in people with mental health problems [19]. As yet though, and despite numerous studies noting the importance of building stigma resistance, this understanding has not been translated into evidence-based interventions that seek to increase stigma resistance. The STORM intervention could feasibly be adapted later for use with other stigmatised populations and thus could have an impact far beyond the ID field.

4.1 Conceptualisation of stigma resistance

Stigma has been described as 'the spoiling of a person's identity' due to profoundly damaging attitudes in society [20]. It occurs within the context of power differentials between those that do the 'labelling' and those that are 'labelled', and results in stereotyping, status loss and discrimination [21]. The negative impact of stigma on its targets has been widely documented, including poorer mental and physical health [22,23], and reduced economic opportunity and overall quality of life [24]. The corrosive impact of stigma also has negative consequences for wider society through long-term health and social care costs [22,25]. While much work and resources have focused on challenging stigma at the interpersonal level and evidence suggests that contact and to a lesser extent education are highly effective in reducing stigma [14,26,27], interventions at the intrapersonal level (i.e. directly with the stigmatised person) have received less attention. Stigma resistance focuses directly on the individual concerned and sees them as being in the driving seat of change.

'Stigma resistance' as a concept has attracted research attention in relation to diverse stigmatised conditions, including HIV/AIDS [28,29,30,31], schizophrenia and other mental health problems

[19,32,33,34,35,36], irritable bowel syndrome [37], parents of children with disabilities [38], and childlessness in women in Southern India [39]. Stigma resistance goes beyond stigma management, which has been likened to "putting up walls to protect oneself from assault" [28]. To manage the negative effects of stigma, including the pain and loss of opportunities resulting from it, the person may employ a range of strategies, for example, withdrawing socially, and avoiding services or treatments [40]. Stigma resistance goes beyond these more passive management strategies and involves proactive acts of resistance, described as "lobbing cannonballs over the walls if necessary" [28]. A number of processes have been hypothesised to be involved in stigma resistance, prominently among them 'stereotype awareness': the capacity to separate one's own thoughts and sense of self from the thoughts of others [19,33]. Recognising in what way one is dissimilar from a stereotype and pushing back by demonstrating 'that's not me' or 'it is only one part of me', protects against the internalisation of stigmatising attitudes [36]. A novel conceptual model of stigma resistance [41] distinguishes resistance at three levels; personal (not believing stigma, focusing on what one thinks about oneself not what others think, developing a meaningful identity and purpose outside of one's diagnosis), peer (using one's experiences to help others), and public (educating others, publicly questioning stigma).

4.1.1 Evidence for the positive effects of stigma resistance

A recent meta-analysis of 48 studies concluded that for people experiencing mental health problems greater resistance to mental health stigma is associated with better overall outcomes [19]. In particular, self-efficacy, hope, insight, reductions in negative symptoms, and better quality of life were associated with higher stigma resistance. Additionally, better outcomes and the capacity to lead more fulfilling lives despite a serious mental health diagnosis were not just explained by lower levels of internalised stigma but more specifically by greater capacity for stigma resistance. Greater stigma resistance has also been found to be associated with reduced symptoms of depression, and increased self-esteem and sense of social power [32,34,42]. These findings can be understood through the empowering, positive effects of members of marginalised groups asserting their rights and needs against those who stigmatise them [42]. Whilst less well substantiated, evidence for the link between stigma resistance and recovery has also emerged from the eating disorder field [36]. Here stigma resistance scores discriminated between those actively struggling with an eating disorder and those recovered, and were negatively correlated with restrictive eating, excessive exercise routines, social

avoidance, and positively correlated with more positive attitudes to seeking treatment and higher self-esteem.

4.2 STORM as an intervention designed to enhance stigma resistance

In the ID field, a few interventions have sought to employ psychosocial approaches to enhance stigma management. These include psychoanalytically informed consciousness raising groups [43], and cognitive behavioural groups [44]. While they may be helpful at an individual level by supporting the person to come to terms with their disability and learn to cope with a stigmatised identity, these interventions do not go beyond stigma management. Furthermore, they were designed to be delivered by highly skilled clinicians and are therefore likely limited in reach.

Standing up for Myself (STORM), our new psychosocial group intervention, works directly with groups of young people and adults with ID to enhance their capacity to manage and resist stigma. STORM was designed from the outset to be scalable by being brief (4 sessions plus one booster session) and suitable for delivery by group facilitators with a modest amount of preparation and training but without requiring any specific qualifications. By being delivered within the context of established groups for people with ID, STORM provides a safe space to tackle a sensitive subject, maximises the potential for peer support, and does not require substantial new delivery mechanisms which would affect its potential future implementation. STORM's theory of change draws on cognitive behavioural therapy [47], e.g. challenging negative beliefs and examining the benefits and disadvantages of different ways of responding to stigma; narrative therapy [48,49], e.g. by separating oneself from a problematized label and developing new stories about oneself; and liberation psychology [50], e.g. by explicitly acknowledging acts of oppression.

To date, we have piloted the STORM programme with 10 groups (N=67 individuals with ID) across the community/third and education sectors. Our pilot indicated that STORM can be delivered in the context of existing groups for people with ID and that it may result in positive outcomes. Only one of 67 participants dropped out. Of pilot participants for whom attendance data were available, 83.6% completed the intervention (i.e. attended three or more of the five STORM sessions). Valid outcome data were provided by 94% of participants at baseline and 74% at three to four months from baseline. Compared to baseline, post-intervention (three to four months from baseline) we observed increased self-efficacy in rejecting prejudice (d=0.81), self-esteem (d=0.4 across all participants, or d=0.8 in those with less than optimal self-esteem at baseline), reduced psychological distress (d=-0.7 in those

showing at least mild distress at baseline), and increased sense of power (d=0.8 in those with less than optimal sense of power at baseline). Participants and STORM facilitators gave very positive feedback about STORM overall and said they would highly recommend it to others. They also suggested some changes to the format of the manual which we have addressed in making minor revisions to the content and format of the manual.

Key outstanding issues to be addressed before it is possible to conclude whether a full trial of STORM is indicated include: 1) recruitment and retention as part of an RCT of STORM versus control; 2) feasibility of outcome measures not used during our pilot (problem based scenarios which we plan to develop to assess stigma resistance in typical everyday situations); 3) feasibility of administering the full catalogue of measures on a 1-to-1 basis (due to resource limitations, during our pilot we administered shortened versions of some of the measures in a group setting); 4) fidelity of delivery in line with the STORM manual and feasibility of proposed methods for assessing fidelity; 5) feasibility of proposed economic evaluation.

5 Study objectives/endpoints and outcome measures

The key aim of this study is to examine whether STORM can be delivered successfully to established groups of people with ID in a range of community, social and educational settings, and in particular whether it would be feasible to conduct a later definitive RCT of the effectiveness and cost-effectiveness of STORM.

5.1 Primary objectives

Primary objectives are to evaluate recruitment and retention, fidelity of STORM delivery in accordance with the manual, acceptability of the intervention and proposed outcome measures, including completion rates for and sensitivity to change of measures not included in the pilot study (e.g., WEMWBS, EQ-5D, service use).

5.2 Secondary objectives

To inform the decision on a primary health related outcome for a potential future definitive study by an assessment of public health importance and the findings from the proposed study.

5.3 Primary outcomes

Feasibility will be addressed as follows:

- Recruitment of providers of groups for people with ID and of group facilitators: Can sufficient providers and group facilitators be recruited over a 9-month period to run up to 8 STORM groups and have 8 groups in the control arm? What factors influence providers' willingness to take part in the research? Can sufficient group facilitators be recruited and trained?
- Recruitment of participants/groups: What are the most effective recruitment pathways to identify suitable groups for people with ID from a range of settings (educational, social/activity based, or self-advocacy groups)? What recruitment rate can be achieved in different settings? What are the characteristics of organisations/groups and participants approached and screened to recruit 16 groups (8 STORM, 8 Control) with an estimated 104 participants?
- Acceptability of research design: Are organisations, facilitators and participants willing to be randomised within the context of an RCT?
- Adherence: What proportion of groups and participants complete at least three of the five STORM sessions?
- Retention: What proportion of groups and participants are retained in the study to the 4-month and 12-month post-randomisation follow-up? Does retention differ between study arms?
- Fidelity of implementation: Can facilitators deliver STORM with a high degree of fidelity to the programme manual? Does fidelity differ by setting (i.e. usual primary purpose of participating groups)?
- Usual practice (UP): What does UP consist of for young people and adults with mild to moderate ID? How is UP different from the STORM programme content?
- Feasibility of outcome measures: Do participants complete the outcome measures for the study? Is there preliminary evidence of differences on these measures between the study arms?
- Feasibility of economic evaluation: What is the feasibility of collecting resource use and health related quality of life data from participants? What is the feasibility of collecting data on the cost of the intervention from providers?
- Estimation of ICCs for the outcome measures and of other parameters needed to inform future sample size calculations, including average cluster size/coefficient of variation.

A qualitative evaluation will contribute information for many of the above points and will be part of a mixed methods detailed process evaluation. In addition, the qualitative data will provide information about the experiences of STORM facilitators, participants, and also the views of their supporters/carers to see whether/how they have understood the intervention.

5.4 Secondary outcomes measures

Health-related and social outcomes:

- Mental wellbeing measured using the Warwick-Edinburgh Mental Well-Being Scale (WEMWBS) [52], a 14-item scale validated for adolescents aged 13+ and adults, with some items simplified in line with other recent studies that have used the scale with people with ID [53,54].
- Self-esteem, measured using 6-item version of Rosenberg self-esteem scale (RSES), validated for people with ID [51].
- Self-efficacy in Rejecting Prejudice (SERP), single self-rated item used in our pilot: "At this moment, how confident do you feel about standing up to prejudice?", rated on a 4-point scale ('not at all confident' to 'very confident').
- Reactions to Discrimination (RtD) 4-item subscale of the ID Self-Stigma Scale, measuring emotional reactions to stigma in people with ID [55].
- Sense of Social Power (SSP): adapted 4-item version of the Sense of Power Scale, to date not yet validated for people with ID [56].

The above scales use 3 to 5-point Likert response scales, with the exception of the original RtD subscale which used a dichotomous yes/no response format.

We will also aim to develop a measure of stigma resistance that is sensitive to change and will pilot this during the proposed study. Informed by methods used in a recent RCT with people with ID [57], we will develop vignette-based scenarios of stigmatising interactions that people with ID may typically experience, and will ask participants how they would be most likely to respond in each situation, with their responses analysed thematically and also categorised as e.g., social withdrawal, ignoring, educating, or confronting. The scenarios, response formats and methods of analysis will be co-produced with our PPI group (see 13.) during the early stages of the study and subsequently piloted with all phase 2 participants (see 9.).

5.5 Measurement for Economic Evaluation

A Service Information Schedule (SIS) will be developed in consultation with the providers of the intervention to fully capture all costs associated with the intervention, will be completed by intervention providers in collaboration with the research team and further explored during qualitative interviews with facilitators.

Client Service Receipt Inventory (CSRI) [58], a self-report measure of use of services and supports. A short version covering a retrospective 3-month period will be developed and adapted for use with input from the PPI Advisory Group. Participants will be asked to provide information about contacts with general health services, mental health services, third sector organisations and education support as well as informal help received from supporters/carers and friends. As part of the 12-month follow-up, we will also ask participants questions to test the potential for consent to accessing routine data concerning health, education and social care use in a possible future study.

EuroQol-Youth (EQ-5D-Y) [59], a self-report measure of health-related quality of life across five domains that are rated on a three-point scale, using simplified wording suitable for this study's sample. Allows for the calculation of quality-adjusted life years (QALYs), a common measure in health economic evaluation.

6 Study design and setting

A cluster-randomised feasibility study, of the manualised STORM psychosocial group programme for people with ID. Community and education sector organisations that work with groups of people with ID will be asked to identify one established group with an average of 6 to 7 members (likely average cluster size) for the study. Groups will be randomised to STORM or the control arm on a 1:1 ratio using variable block randomisation in which unit of randomisation is the group. The control group will receive UP + access to STORM after the follow-up period (wait-list control). The proposed methods for economic evaluation will be tested and a process evaluation, using mixed methods, will be carried out to examine the delivery of the intervention and adherence, as well as stakeholder views on the acceptability of the intervention and on barriers and facilitators that may affect its future implementation and plans for a future definitive study.

6.1 Risk assessment

A Study Risk Assessment has been completed to identify the potential hazards associated with the study and to assess the likelihood of those hazards occurring and resulting in harm. This risk assessment includes:

- The known and potential risks and benefits to human participants
- How high the risk is compared to normal standard practice
- How the risk will be minimised/managed

This study has been categorised as low risk, where the level of risk is comparable to the risk of standard care. A copy of the study risk assessment may be requested from the Study Manager. The study risk assessment is used to determine the intensity and focus of monitoring activity (see section 23.1).

7 Site and Investigator selection

This study will be carried out within the UK. Information about the study will be disseminated to organisations in the third, education and social sectors that provide services to people with ID, as detailed in section 9. All settings who are interested in participating in the study will be required to complete a registration form to confirm that they have existing groups for people with ID that meet the inclusion criteria (see section 8), adequate resources and experience to conduct the study.

Occasionally during the study, amendments may be made to the study documentation. The Study Manager will issue the latest version of the documents as soon as they become available. It is the responsibility of the Study Manager and Chief Investigator to ensure that they obtain local relevant approval for the new documents.

The Chief Investigator (CI) is responsible for the overall conduct of the study, compliance with the protocol and any protocol amendments. In accordance with the principles of GCP certain responsibilities may be delegated to an appropriate member of the study staff. Delegated tasks will be documented in a delegation log and signed by all those named on the list. The CI will be familiar with the protocol and the study requirements, and will remain up to date with the principles of good clinical practice. It is the CI's responsibility to ensure that all study staff are adequately informed of the protocol and study related duties. All staff involved in the study will follow the local University and their employer's procedures and policies for lone workers.

8 Participant selection

Participants are eligible for the study if they meet all of the following inclusion criteria and none of the exclusion criteria apply. All queries about participant eligibility should be directed to the Study Manager before randomisation/registration.

8.1 Inclusion criteria for groups/organisations

Groups that wish to take part in the study will:

- Be in place already, i.e. they are not specifically formed for the purposes of the intervention or the research;
- Intend to continue meeting as a group for at least three further months;
- Have at least four members with ID who wish to participate in the intervention, and no more than ten members to allow for full engagement in group discussions and other STORM activities;
- Be willing to replace five of their usual meetings with STORM for the study;
- Have a group facilitator who consents to taking part and who is willing to facilitate the STORM intervention;
- The facilitator is willing to complete two 2-hour training sessions (a mix of on-line and face-to-face training) and to receive 2 to 3 hours of STORM supervision;
- Facilitators will also be expected to be willing to complete the study records, audio record sessions, and to participate in a qualitative interview 4 to 6 months from baseline.
- The organisation which hosts participating groups must have the resources to support the study and must be willing to free up the group facilitator for STORM training and supervision.

8.2 Inclusion criteria for individuals

Participants will:

- be aged 16+ years;
- have an ID as defined by an administrative definition, in terms of receipt of specialist services for people with ID within the education, social care, third or health sector;
- be able to complete the outcome measures (with support), attend to short films, and engage in a discussion-based group programme – abilities likely to equate to mild to moderate ID (severity of ID will not be formally assessed as this is too resource intensive);

- have sufficient expressive and receptive communication skills in English (reading skills not required) to allow participation in STORM and completion of measures;
- be a member of an established group for people with ID (educational, activity, social or self-advocacy focused).
- have capacity to provide informed consent to participation in the study;
- provide informed consent to taking part in the study.

Some individuals whose group is randomised to the intervention arm may not have capacity to consent to participating in the research but may wish to take part in STORM. In such cases, the individual will be included in the STORM group but not the research, presuming careful discussion with the facilitator concludes that the potential benefits of taking part outweigh any risks and that participation in STORM is in the person's best interests.

8.3 Exclusion criteria for groups/organisations

Groups will be excluded if:

- they are run as part of NHS services;
- some of their regular members decline taking part in STORM and it is not possible to find alternative meeting times to run STORM.

8.4 Exclusion criteria for individuals

Participants will be excluded if they:

- are unable to communicate using English (and adaptations to meet their communication needs cannot be put in place for the respective group);
- do not give consent or are found not to have capacity to consent.

Where participants consent to participating in the study but not to having STORM sessions audio recorded, alternative ways to assess fidelity will be explored (e.g. through a member of the research team observing sessions with group members' and the facilitator's consent).

9 Recruitment, Screening and registration

9.1 Participant identification

Recruitment will take place through Mencap's national network, social media channels and events, and through direct approaches to local Mencap groups, other third sector organisations for people with ID (e.g. Macintyre, Mcch, Camden Society, Westminster Society), local People First and Speaking Up groups, and approaches to secondary schools and colleges that provide educational activities to young people with ID across the South East of England. We will also promote the study through our UCL Unit for Stigma Research website, blog, Twitter feed, Facebook page and newsletter, and at events and via publications directed at providers of services for young people and adults with ID. Other networks of the research team will also be used, as relevant.

9.2 Screening logs

To screen potential participants, for each organisation/group expressing interest in participating, a member of the research team will initially discuss the study and inclusion criteria with staff from the organisation. They will describe the communication skills required to participate in the study and provide some examples of tasks similar to those in the intervention and measures to check that potential participants are likely to meet the inclusion criteria, particularly with regard to the cognitive and communication skills required to give informed consent, engage with the intervention and complete the outcome measures.

A screening log of all ineligible and eligible but not consented/not approached will be kept so that any biases from differential recruitment will be detected. Logs will not contain identifiable information.

9.3 Recruitment rates

A total of approximately 104 participants will be recruited at an expected rate of 17 per month in phase 1 (Nov 2019-January 2020) and 17 per month in phase 2 (April- June 2020).

9.4 Informed consent and ethical considerations

The key ethical issues for the proposed project are the potentially upsetting nature of discussing negative experiences, being asked to complete measures of psychological functioning and wellbeing, and informed consent. We recognise that having a space to raise and discuss past negative experiences and interactions with others may cause distress and have paid careful attention to this in

designing the intervention and worked closely with our advisers with ID. As a result, each session has been designed so as to finish on a positive note, the manual includes guidance for facilitators on managing distress and this will also be addressed in the facilitator training. Importantly, by being delivered to existing groups by facilitators who are familiar with participants, natural support will be in place. In addition, participant feedback received during our pilot suggests that STORM participants found it useful to have a space to discuss concerns and negative experiences they may have had in the past but found difficult to raise.

Regarding potential distress caused in response to the outcome measures - these will be administered by research assistants who will be trained in sensitively asking people with ID about such matters. In addition, the group facilitator who is familiar with participants will be present during completion of the measures and will also be able to monitor participants for signs of distress and provide support there and then, as well as arrange additional support should this be called for.

Some participants might experience distress as a consequence of participating in STORM (for example, because they are reminded of traumatic past experiences). This will be managed by:

i) explaining to all participants at the outset that it is possible that they may become upset by some of the material and discussions (we will do so in any case as part of the consent process but will reiterate this in session 1) and advising participants what to do if they experience distress, both verbally and through a brief Easy Read advice sheet which they can take away;
ii) providing the information sheet for carers in this context and suggesting that participants may find it helpful to pass this to their supporter/carer and to talk to them about STORM whenever they feel they would like some support;
iii) training STORM group facilitators and researchers how to notice, respond and offer support;
iv) reiterating this information through detailed guidance on supporting group members provided in the STORM manual;
v) explaining to participants that we may need to contact a supporter/carer and/or their GP if we should become concerned about their wellbeing, and informing them in a sensitive manner if this is called for. Such actions will be taken in careful discussion with the group facilitator and in adherence with local safeguarding policies and procedures.

In addition, the STORM manual contains a debrief at the end of every session ensuring that facilitators always ‘check In’ with participants at the end of each session and offer an opportunity for any group

member to receive additional support. Training and information provided in the manual will also outline and reinforce good practice in group facilitation and how to respond in situations when participants may be distressed by any of the materials presented or by recounting their own past experiences, or to any disclosure participants may make.

Consent will be obtained by trained members of the research team. The consent process will be clearly illustrated in a flow chart, and all research staff will be trained in its use. The flow chart will be finalised with input from the PPI and Study Management Groups. The research team will explain to potential participants that they may become upset by some of the STORM material and discussions, that the team may need to contact a supporter/carer and/or their GP if they should become concerned about their wellbeing, and emphasise their right to withdraw from the study at any point. Information sheets will be presented face-to-face by a member of the research team at a pace that is commensurate with the communication needs of people with ID and potential participants will be provided with an additional information sheet designed for family carers/supporters, which they will be invited to take away and discuss with a supporter/carer before being asked whether they consent to taking part. It will be at participants' discretion whether these are shared with carers/supporters and their wishes respected in line with the empowerment values inherent in the project.

Recruitment of established groups to the study poses many advantages and has a close fit with the logic model but also poses ethical risks, particularly the risk that organisations and groups collectively express interest in taking part but individual members of the respective group do not wish to participate in the STORM programme, or do not have capacity. In such cases group members who wish to participate in STORM but not the research, or who do not have capacity will be included in the STORM group but not the research as long as careful discussion with the facilitator, and where necessary separate discussion with the individual (overseen by the CI who is a clinical psychologist fully trained and experienced in capacity assessments) concludes that participation in STORM is in their best interests and does not pose any significant risks to the individual. In cases where groups collectively wish to take part but individual group members decline participating in STORM, initially we will attempt to find alternative times for the group to meet to enable those who wish to take part. Should this not prove possible, the respective group will not be included in the study in order to prevent individuals who do not wish to participate in STORM missing out on their usual group meetings or feeling under undue pressure to consent to taking part in STORM.

As part of the 12-month follow-up, we will also ask participants questions to test the potential for obtaining consent to access routine data concerning health, education and social care use in a possible future study.

9.4 Randomisation

All baseline assessments will be completed before randomisation. Groups will be randomised to STORM or the control arm on a 1:1 ratio using variable block randomisation in which unit of randomisation is the group.

10 Withdrawal & lost to follow-up

10.1 Withdrawal

Participants have the right to withdraw consent for participation in any aspect of the study at any time. The participant's care will not be affected at any time by declining to participate or withdrawing from the study. If a participant initially consents but subsequently withdraws from the study, a clear distinction must be made as to what aspect of the study the participant is withdrawing from:

- Withdrawal from the intervention (attendance at the STORM group) only: unless they also expressedly withdraw from further data collection they would continue to participate in the research evaluation
- Withdrawal from future follow-up assessments
- Withdrawal of permission to use data already collected
- Withdrawal of consent to all of the above

Groups similarly have the right to withdraw from participation in the study. In all instances a withdrawal form should be completed for each participant on the participant's behalf by the research team based on information provided by the participant. This withdrawal form should be sent to the Study Manager. Any queries relating to potential withdrawal of a participant should be forwarded to the Study Manager. It is important to collect safety data ongoing at the time of withdrawal, especially if the participant withdraws or is withdrawn because of a safety event.

10.2 Lost to follow-up

Participants who, despite three attempts to obtain outcome data from them, do not complete the follow-up outcome measures within the specified timeframe (12 months + 2 month) will be considered lost to follow-up. Participants who appear lost to follow-up will be asked if they would be willing to complete the Rosenberg Self-Esteem scale and the WEMWBS as key outcomes of interest.

11. Study Intervention

11.1 STORM

STORM is a manualised psychosocial group intervention developed with close input from people with ID and experienced facilitators of groups for people with ID. The manual and resources were designed for delivery by group facilitators who have experience of facilitating groups for people with ID but who do not require any specialist qualification. The intervention is delivered to established groups to ensure members feel comfortable and safe discussing painful topics and able to offer peer support to each other, and that facilitators who know them can monitor their responses and offer additional support where necessary. Peer support available through a group intervention is seen as an integral part of STORM with hypothesised benefits for wellbeing, sense of self-worth, and responses to stigma, based on evidence from the mental health field [45, 46].

STORM consists of four weekly 90-minute sessions and a 90-minute booster session (delivered around four weeks after session 4) and involves: (a) watching short films of people with ID talking about the meaning of ID to them personally, their first hand experiences of interacting with others (both positive and negative), and how they deal with negative interactions with others; (b) group discussions of this material, guided by questions posed by the group facilitator as per the manual; (c) sharing of personal experiences; (d) problem solving in relation to different possible responses to stigmatising experiences; and (e) action planning for managing/resisting stigma in future either individually and/or as a group. STORM uses short film clips (of 2 to 7 minutes in length) extracted with permission from the films' original makers/producers from existing film footage produced with and by people with ID.

Table 1. STORM Programme Overview

Session 1: What does 'learning disability'[1] mean to people with learning disabilities? What does it mean to me?
Key message: *My learning disability is only one part of me.*
Session 2: How are people with learning disabilities treated?
Key message: *It's not OK for people to treat me badly. I don't have to put up with it.*
Session 3: How do people with learning disabilities respond to being treated negatively?
Key message: *I can stand up for myself when people treat me badly.*
Session 4: What am I already doing when others treat me in a way I don't like? What else do I want to try?
Key message: *I can make a plan to help me stand up for myself. People I trust can help me with it.*
Booster Session: What worked and what got in the way of my plan?
Key message: *Things can get in the way of my plan. Talking to others can help me decide what to do next and not give up.*

The STORM manual is available as a pdf document, and is supported by an on-line web-based version that has all training and preparation materials, film clips, session materials, information for participants in an accessible Easy Read format, and optional activity and work sheets in a format designed to make it as easy as possible for facilitators to deliver each session in accordance with the manual. These materials have been fully updated following the feedback from our recently-completed pilot study.

STORM is delivered by staff in education, social care and third sector organisations who have experience of facilitating groups for people with ID and who are familiar with members of their STORM group. They do not require any specific qualifications and will receive 2 x 2 hours of training in small groups (delivered as a combination of individual web based training and sessions conducted in small groups of up to 4 facilitators, face to face wherever possible or via Skype or Zoom), the manual, all resources and materials, and two to three individual supervision sessions (face to face or by telephone or Skype/Zoom). Training and supervision will be delivered by Mencap, our intervention delivery partner.

[1] In the STORM intervention, the everyday UK term for ID 'learning disability' is used so that it is familiar to participants

Participating groups will differ in terms of their usual primary focus: educational, social/activity-based, or self-advocacy, some groups participating in STORM may continue with their usual activities in addition to STORM. Recruitment to the study, retention of participants, and delivery of the STORM programme is likely to be subject to different parameters and constraints for different groups. For education based groups run in college settings, for example, the STORM programme would most likely be mapped onto learning objectives aligned with the PHSE domain of the national curriculum. Social/activity based and self-advocacy groups are likely to be run by Mencap (the main delivery partner) national and local groups, and other smaller third sector or social care providers who have a focus on providing access to positive relationships and activities for people with ID, or on supporting them in advocating for their equal rights. Testing the feasibility and delivery of STORM for different types of groups and environments and exploring preliminary outcomes will allow assessment of the STORM programme's potential as a public health intervention that could be delivered to scale and to explore participant and setting factors that may affect its delivery and outcomes. Access to STORM will only be available via the study and, to avoid potential within-site contamination between study arms, we are taking the precaution of only recruiting one group per local site.

11.1 Comparator intervention

The comparator intervention will be Usual Practice (UP) - participants will attend their usual group sessions as well as other services they may be engaged with but without receiving STORM. Records will be kept by facilitators in the control group to monitor group activities and check for potential overlap between UP and STORM contents. This will be done using a summary sheet provided for facilitators. Contents of group sessions will be further explored in qualitative interviews with control arm facilitators. In addition, services receipt data collected at baseline and 12 months will be used to fully describe UP. All this information will be used to fully describe UP and this information will then be considered in the design of a potential definitive study.

Groups in the control arm will be given access to the STORM manual and resources to use if they wish after completion of all measures and interviews, as long as there is no suggestion of harm in the STORM arm.

12 Study procedures

12.1 Baseline and follow-up assessments

Groups and participants will be screened during a telephone interview with group facilitators, conducted by research staff (see section 8 above for inclusion/exclusion criteria). If eligible, initial information about the study will be presented to potential participants by the group facilitator. If willing to take part, a recruitment/ baseline interview will be arranged and informed consent and baseline measures taken. All outcome measures and the EQ-5D-Y will be completed by participants at baseline, at around four months (- 2 weeks and + 1 month) and 12 months (+- 1 month) post-randomisation, with an allowance to account for participant availability and possible late collection of data, e.g. due to illness. All measures will be administered by a research assistant to participants individually in a flexible manner, where called for reading items one by one and supporting participants in recording their responses, or offering much less support where participants do not require this and prefer to read items and record their responses without support.

Figure 1. Schedule of enrolment, interventions and assessments[2]

Procedures	**Assessments**				
	Screening	**Baseline**	**Intervention**	**Follow Up**	
				4 Months	**12 Months**
Informed consent	X				
Eligibility	X				
Informed Consent		X			
Demographics		X			
WEMWBS		X		X	X
RSES		X		X	X
SERP		X		X	X
RtD		X		X	X
SSP		X		X	X
EQ-5D-Y		X		X	X

[2] Taken from the HRA CTIMP protocol template (2016).

CSRI		X			X
Intervention			X		
Audio recording on intervention sessions					
UP session summary			X		
Participant qualitative interviews				X	
Group facilitator qualitative interviews				X	
Qualitative interviews with supporters of STORM participants				X	

Participants will receive a £10 cash payment at each assessment point in recognition of the time taken to complete the measures at baseline, four and 12 months. In addition, participants and facilitators who take part in qualitative interviews will receive a £10 cash payment or will be able to nominate a charity to have £10 donated to.

12.2 Process evaluation

A mixed methods process evaluation will examine the following key aspects of the feasibility of conducting a definitive study of STORM: (1) intervention recruitment, adherence and reach; (2) intervention fidelity; (3) intervention mechanisms and acceptability; (4) feasibility of implementing STORM within a definitive RCT. The evaluation will be guided by the MRC guidance [Ref] and will help refine the intervention logic model.

Re (1): Adherence will be assessed by group facilitators recording participants' attendance at each session. Qualitative interviews with up to 16 group facilitators (from both study arms) will explore recruitment and barriers/facilitating factors for engaging participants in the study. Recruitment and engagement processes will also be explored through interviews with up to 16 STORM participants (see below). Demographic information about participants will be examined to assess intervention reach.

Re (2): To assess fidelity to the STORM manual, we will develop a checklist of core requirements for (i) adherence to the manual, (ii) group process, and (iii) facilitator engagement with group members. The checklist will be used to rate audio recordings of sessions to determine whether core elements are fully present/partly present/absent. The checklist will be adapted from an existing fidelity instrument

developed for group interventions and taking into account the particular social and communication skills of people with ID [60]. Raters will be trained to a high level of initial reliability and then their ratings of session recordings will be checked periodically for drift. STORM sessions will be audio recorded and fidelity rated for three sessions per group, by randomly selecting one of the first two sessions, one of sessions 3 or 4, and all of the booster sessions. Quantitative analysis will explore the variation of fidelity scores across group types and the association between fidelity scores and outcomes.

Re (3): Structured interviews with up to 16 STORM participants (aiming for 2 per group including those who dropped out of the study), up to 8 STORM facilitators, and up to 8 group facilitators from the control arm will be conducted to seek their views on: recruitment processes, experiences of study participation, and barriers/facilitators to STORM implementation, and to obtain a more detailed description of UP. Interviews with STORM participants will be conducted shortly after completion of the booster session (around 3 to 4 months from baseline); to ensure maximum recall by participants, reminders of all STORM sessions will be provided in view of common memory problems in people with ID. Interviews with group facilitators will be conducted 4 to 6 months from baseline. Approximately 8 supporters/family carers of STORM participants will be interviewed 4 to 6 months from baseline to access their views about STORM and its impact on the person they support. This will include occasions when they may have provided support to participants during or after STORM sessions, including instances when carers/supporters may have had to deal with negative consequences from STORM participants standing up for themselves.

Potential future improvements to the content or delivery of STORM sessions and reasons for these will also be explored during qualitative interviews with STORM facilitators. Data on adaptations made in response to participant characteristics (e.g. age) and setting demands will allow us to understand key influences on STORM programme implementation and mechanisms and to refine the manual, materials, and logic model, where indicated. During interviews with STORM participants and facilitators we will also ask about the perceived value, benefits and harm or unintended consequences of the STORM intervention to develop a full understanding of the likely mechanisms of change and to ensure these are fully measured in a full study.

Re (4): Data on recruitment (1), intervention fidelity and factors shaping implementation of the intervention (2) and intervention mechanisms (3) will be used to help inform assessment of the feasibility of implementing STORM within a definitive study.

Other data for the process evaluation will include:

1. Data on the uptake of supervision by STORM group facilitators;

2. Records of the key contents of group sessions in the control arm will be kept by facilitators, using a summary sheet we will provide and session contents will be further explored in qualitative interviews with control arm facilitators. This will help identify the extent of any contamination through the completion of activities that may explicitly or implicitly increase participants' capacity to manage and resist stigma;

3. Reasons for drop out from the research and the time point at which participants dropped out will be recorded.

13 Safety reporting

In the unlikely event that any SAEs related to the intervention or research procedures should occur, the CI is responsible for ensuring that all site staff involved in this study are familiar with the content of this section. All SAEs must be reported immediately (and within 24 hours of knowledge of the event) by the respective group facilitator or the Mencap intervention lead to the study team.

SAEs will be assessed at all follow-up time points, and intervention delivery staff will be trained to report these directly to the study team at any point during the study. Rates of SAEs by study arm will be reported to the SSC, and if required, to the REC. Additional information about the potential harm of the intervention will be collected through qualitative interviews with all stakeholders.

13.1 Definitions

Term	Definition
Adverse Event (AE)	Any untoward medical occurrence in a participant or clinical study participant administered an intervention which are not necessarily caused by or related to that product
Serious Adverse Event (SAE)	Any adverse event that - • Results in death • Is life-threatening*

	• Requires hospitalisation ** • Other medically important condition***

***Note:** The term 'life-threatening' in the definition of 'serious' refers to an event in which the study participant was at risk of death at the time of the event or it is suspected that use or continued receipt of the intervention would result in the subject's death; it does not refer to an event which hypothetically might have caused death if it were more severe.

**** Note:** Hospitalisation is defined as an inpatient admission, regardless of the length of stay, even if the hospitalisation is a precautionary measure for continued observation. Pre-planned hospitalisation e.g. for pre-existing conditions which have not worsened, or elective procedures, does not constitute an SAE.

***** Note:** other events that may not result in death, are not life-threatening, or do not require hospitalisation, may be considered as an SAE when, based upon appropriate medical judgement, the event may jeopardise the participant and may require medical or surgical intervention to prevent one of the outcomes listed above.

13.2 Causality

The assessment of whether or not an SAE is a consequence of receiving the intervention will be provided by the CI.

Relationship	Description	Reasonable possibility that the SAE may have been caused by the intervention?
Unrelated	There is no evidence of any causal relationship with the intervention	No
Unlikely	There is little evidence to suggest there is a causal relationship with the intervention (e.g. the event did not occur within a reasonable time after receipt of the intervention). There is another reasonable explanation for the event (e.g. the participant's clinical condition, other concomitant treatment).	No
Possible	There is some evidence to suggest a causal relationship with the intervention (e.g. because the event occurs within a reasonable time after after receipt of the intervention). However, the influence of other factors may have contributed to the event (e.g. the participant's clinical condition, other concomitant treatments).	Yes
Probable	There is evidence to suggest a causal relationship and the influence of other factors is unlikely.	Yes
Definite	There is clear evidence to suggest a causal relationship and other possible contributing factors can be ruled out.	Yes

13.3 Reporting procedures

Any queries concerning adverse event reporting should be directed to the Study Manager.

All SAEs, whether expected or not, should be recorded on the relevant report form and followed up to resolution wherever possible. The CI (or delegated member of the SMG) should sign and date the SAE reporting form to acknowledge that he/she has performed the seriousness and causality assessments. SAEs should be reported from time of signature of informed consent, throughout the treatment period.

An SAE form is not considered as complete unless the following details are provided:

- Full participant study number
- A Serious Adverse Event
- A completed assessment of the seriousness, and causality as performed by the CI (or another appropriately medically qualified doctor registered on the delegation log).

Only reports of related and unexpected SAEs should be submitted to the REC. These should be sent within 15 days of the CI becoming aware of the event.

14 Statistical considerations

14.1 Randomisation

This is a cluster-randomised feasibility study. Groups will be randomised following completion of baseline assessments, using a 1:1 allocation ratio to STORM or Control. Randomisation lists will be prepared by the study statistician and will be generated using block randomisation, stratified by the primary purpose of the group – self advocacy or 'other' (e.g., educational, activity based, social). As the study statistician is to remain blind to allocation until the point all analyses are completed, the Senior Research Fellow at CTR will assign the STORM/Control allocation to the randomisation list. Following enrolment of a group, recruitment and consent of participants within a group, and collection of baseline data, groups will be allocated to intervention / control by the Data Manager at CTR. The Study Manager at UCL will notify group facilitators and arrange the implementation of intervention, as appropriate.

14.2 Blinding

Participants and group facilitators will not be blind to allocation. Outcome data will be collected by research assistants who will, wherever possible, remain blind to allocation and will record any instances of unblinding. They will remain blind to allocation up until the point that all outcome data

have been collected. The statistician carrying out the main statistical analyses will remain blind to allocation up until the point all analyses are completed.

14.3 Sample size

As this is a feasibility study, we seek to provide estimates of key parameters for a future study and have not conducted a formal a priori power calculation. A sample size of 16 groups (N=104) will allow us to estimate a recruitment rate of 80% of eligible participants (i.e. 16 groups recruited out of 20 approached) with a 95% CI of +/- 17.5% (i.e. from 62.5% to 97.5%). Assuming that 75% of participants provide outcome data at 12-months post-randomisation, randomising 104 participants will allow for the 95% CI to be estimated to within +/- 8.3%.

14.4 Missing, unused & spurious data

All analysis will be performed on complete cases. No imputation of missing data will be carried out.

Further detail will be provided in the Statistical and Health Economics Analysis Plan (SHEAP).

14.5 Procedures for reporting deviation(s) from the original SAP

These will be submitted as substantial amendments where applicable and recorded in subsequent versions of the protocol and SAP.

14.6 Termination of the study

There will be no formal 'stopping rules' or 'discontinuation criteria' for individual participants, parts of the trial and entire trial. Any decision to terminate the trial will be reached by the SSC in discussion with the study's funder.

14.7 Inclusion in analysis

All randomised participants' data will be included in the analysis.

15 Analysis

15.1 Main analysis

As this is a feasibility study, analysis of the primary outcomes of interest (recruitment, retention, adherence, fidelity to STORM programme manual, characterisation of UP, data completeness) will be descriptive in nature. Continuous data will be reported as means and standard deviations, or medians

and interquartile ranges, as appropriate. Categorical data will be reported as frequencies and proportions. All data will be reported both overall, per arm, and by group type. Feasibility outcomes will be estimated with their associated 95% confidence intervals and these will be compared against progression criteria. No formal hypothesis testing will take place.

The study will be reported in accordance with the CONSORT extension for randomised pilot and feasibility studies.

Explanatory analysis of participant reported outcome measures to be used in the main study will be based on the modified intention to treat (MITT) principle, with those providing outcome data being included in the analysis. Mean scale scores will be compared between arms at both 4 months and 12 months, by fitting two-level regressions models with participants nested within community organisations. The model will adjust for baseline scores and the randomisation factor, group type (self-advocacy group or group with another primary purpose). Results will be reported as adjusted mean differences and 95% confidence intervals, focusing on effect sizes and their precision rather than p-values. Intra-cluster correlation coefficients will be reported with associated 95% confidence intervals, with sources of variation explored using both quantitative and qualitative data.

Regression models will be fitted to explore baseline factors associated with intervention receipt and retention in the study at the 4 and 12-month follow-up time points. Findings will be used to inform any study design modifications required in the main study.

A detailed Statistical Analysis Plan will be written and signed off prior to undertaking any analysis.

15.1.1 Sub-group & interim analysis

No subgroup or interim analysis will take place.

15.2 Analysis of Process Evaluation data

With appropriate consent, all interviews will be audio-recorded, transcribed fully, and anonymised for analysis. The AI Software Trint will be used to transcribe interview recordings. Framework analysis will be used to analyse interview data, supported by use of the software NVivo. The analysis of interviews with STORM participants and STORM group facilitators will summarise their views on barriers/facilitators to STORM implementation and the perceived value, benefits and harm or unintended consequences of the STORM intervention. The analysis of interviews with group

facilitators in the control arm will summarise facilitator views on recruitment processes and experiences of study participation. Analysis of interviews with supporters/family carers of STORM participants will summarise their views about STORM and its perceived impact on the person they support, occasions when they may have provided support in relation to participant responses to STORM sessions, and any adverse consequences, including occasions when carers/supporters may have had to deal with negative consequences from STORM participants standing up for themselves.

15.3 Economic analysis

The feasibility of economic evaluation will be assessed using rates of completion of information about the cost of the intervention (SIS) and rate of completion of information about access to formal and informal sources of support (CSRI).

A comprehensive intervention cost for STORM will be calculated based on SIS data, including information on staff salaries, on-costs, overheads, training costs, materials and travel time.

We will report the proportion of returned CSRIs and the proportion of questions completed at each time point. The proportion of study participants reporting contacts with a given service will be reported to determine whether participants rely primarily on formal services or informal care for support.

The findings will show whether it is feasible to assess cost-effectiveness from a) a public sector perspective or b) a wider societal perspective in a full trial. Costs associated with service use will be calculated by attaching an appropriate unit cost – drawn from national compendia [61, 63] or calculated using an equivalent approach based on the principle of long-run marginal opportunity costs [64] - to each instance of service use. These initial findings can inform a power calculation for the definitive RCT.

15.4 Criteria for progression to a definitive trial

The following operational criteria, using a traffic light system [62], will inform the decision whether to progress to a definitive trial of the effectiveness and cost-effectiveness of the STORM intervention.

	Green (Go)	Amber (Amend)	Red (Stop)
1. Recruitment	90-100% of target sample achieved	70%-89% of target sample achieved	<70% of target sample achieved within study recruitment periods

	within study recruitment periods	within study recruitment periods	
2. Adherence	80%+ of participants attend at least 3 of 5 STORM sessions	60%-79% attend at least 3 of 5 STORM sessions	<60% attend at least 3 of 5 STORM sessions
3. Retention	75%+ of participants retained for follow-up at 12 months	50%-74% retained for follow-up at 12 months	<50% retained for follow-up at 12 months
4. Fidelity	90%+ of STORM components rated as partially or fully present	70%-89% of STORM components partially or fully present	<70% of STORM components partially or fully present
5. Outcomes	80%+ of collected outcome data are usable	70%-79% of collected outcome data are usable	<70% of collected outcome data are usable

If the Study Steering Committee (SSC) concludes that progression to a full RCT is feasible, the information gathered during this study will be used to inform the protocol for that trial. Where criteria are only partly met (amber), a discussion will be had with the SSC regarding potential reasons for this and proposed amendments to study procedures to ensure the targets could be achieved in a possible full trial.

16 Data Management

Source Data is defined as "All information in original records and certified copies of original records of clinical findings, observations or other activities in a clinical study necessary for the reconstruction and evaluation of the study. Source data are contained in source documents." There is only one set of source data at any time for any data element, as defined in site source data agreement.

Study data	*Source Data*		
	CRF	*Encrypted voice recordings*	*SAE form*
Outcome measures	*X*		
Interviews		*X*	
Adverse events			*X*

16.1 Data collection

All outcome data will be entered into a secure, encrypted bespoke online database developed by the clinical trials unit, based on paper or electronic copies of the measures completed by participants. Fidelity checks and data cleaning will be performed as detailed in the data management plan, and according to CTR SOPs (GCP and GDPR compliant). Electronic data will be stored on Cardiff University servers and access will be password protected (restricted only to those who need direct access, who will be provided with individual log-ins). Paper copy forms will be stored in locked filing cabinets at UCL and destroyed following data entry.

We will aim to make research data available wherever possible and in line with the NIHR position on sharing data, such that the sharing of research data must: protect the confidentiality and privacy of individuals; respect the terms of consent by individuals who are involved in research; be consistent with relevant legal, ethical and regulatory frameworks; and guard against unreasonable costs.

16.2 Completion of CRFs

Assessments will be completed using web-based CRFs, wherever possible. In the event that the web-based system is not accessible, paper-based CRFs will be used to record the data and the research assistant will enter this data on a web-based CRF at the earliest opportunity. All outcome measures and the EQ-5D-Y will be completed by participants at baseline, at around 4 months and 12 months post-randomisation. The modified CSRI will be completed by participants at baseline and 12 months. All CRFs will be administered to participants at site by the UCL RA. If paper-based CRFs are used, this data will then be inputted into the web-based system by the UCL RA once it is accessible.

In accordance with the principles of GCP, the CI is responsible for ensuring accuracy, completeness, legibility and timeliness of the data reported to the CTR in the CRFs. CRF data will be checked for missing, illegible or unusual values (range checks) and consistency over time.

If missing or questionable data are identified, a data query will be raised on a data clarification form. The data clarification form will be sent to the UCL RA by email. The response to the data query should be completed on the data clarification form. Any paper-based CRFs should not be altered.

All answered data queries and corrections should be signed off and dated by the UCL RA. The completed data clarification form should be scanned and returned to the CTR by email. A copy of the original data clarification form should be retained at UCL along with the participants' CRFs.

The CTR will send reminders for any overdue data. It is UCLs responsibility to submit complete and accurate data in timely manner.

Detailed plans for data entry and handling are located in the study specific Data Management Plan.

17 Protocol/GCP non-compliance

The CI should report any non-compliance to the study protocol or the conditions and principles of Good Clinical Practice to the CTR in writing as soon as they become aware of it.

18 End of Study definition

The end of study is defined as the completion of the follow-up group data collection questionnaire from the final participant.

Once the final report has been approved by the study funder, a copy will be sent to the Sponsor. A summary report of the study will be provided to the REC within one year of the end of the study.

Sponsor must notify the main REC of the end of a clinical study within 90 days of its completion or within 15 days if the study is terminated early.

20 Archiving

All data will be kept for 15 years in line with UCL and CTR Research Governance Framework Regulations for clinical research. This data will be stored confidentially on password protected servers maintained on the Cardiff University Network. Files will only be accessible to researchers responsible for the running of the study and the CI. All procedures for data storage, processing and management will comply with the General Data Protection Regulation 2016. All paper records will be stored in a locked filing cabinet, with keys available only to researchers and the CI. The Study Statistician will carry out the analyses. All essential documents generated by the study will be kept in the Trial Master File.

21 Regulatory Considerations

21.1 Ethical and governance approval

Ethical approval for the study was granted by University College London (UCL), the lead research site (Ref: 0241/005). Where necessary, additional approvals will be sought from the management/board of participating organisations.

21.2 Data Protection

UCL and the CTR will act to preserve participant confidentiality and will not disclose or reproduce any information by which participants could be identified, except where specific consent is obtained. Data will be stored in a secure manner and will be registered in accordance with the General Data Protection Regulation 2016. The data custodian and the translational sample custodian for this study is the UCL sponsor.

21.3 Indemnity

UCL has in force a Public and Products Liability policy which provides cover for claims for "negligent harm" and the activities described in this study protocol are included within that coverage subject to the terms, conditions and exceptions of the policy.

21.4 Study sponsorship

UCL will act as Sponsor for study. The Sponsor has/will be delegating certain responsibilities to Cardiff University (CTR), the Chief Investigators, host sites and other stakeholder organisations as appropriate in accordance with the relevant agreement that is informed by regulation and study type.

21.5 Funding

This project was funded by the National Institute for Health Research Public Health Research (NIHR PHR) Programme. Cost associated with training, supervision and support for STORM delivery will be met by Mencap. Participating organisations will meet the costs of intervention delivery, including facilitator time, venues and materials.

22 Study management

The study will adhere to NIHR guidelines for research governance (including regarding project steering and data monitoring committees) and will be conducted according to Centre for Trials Research (Cardiff University) Standard Operating Procedures (SOPs), study-specific SOPs will be developed as required. The Study Manager will be responsible for day-to-day running and co-ordination of the study.

The Project Team (PT) will meet fortnightly and will include the CI, Statistician, Senior Study Manager, Study Manager, Data Manager and RA. The PT will discuss all day-to-day management issues and will refer any key management decisions to the SMG.

22.1 SMG (Study Management Group)

The Study Management Group (SMG) will meet bi-monthly and will include all investigators, all employed project staff and two representatives of the PPI Advisory group to discuss study progression and key management issues. SMG members will be required to sign up to the remit and conditions as set out in the SMG Charter.

22.2 SSC (Study Steering Committee)

A Study Steering Committee (SSC) will be established and will meet three times during the study. It will comprise of an independent chair with expertise in ID research and in studies in the ID field, and other independent members: three clinicians/researchers who are expert in the ID field, a statistician, health economist and a member with ID. The CI and Study Manager will attend the SSC as observers. The SSC will review the conduct of the study, provide overall oversight and advice through its independent chair. The SSC will also oversee data monitoring and ethics. SSC members will be required to sign up to the remit and conditions as set out in the SSC Charter.

22.3 PPI (Patient and Public Involvement)

A PPI Advisory group will be established and will meet around eight times during the study, more frequently at the start to provide input on all materials and procedures. It will comprise of existing STORM advisers with ID, and will be attended by the Study Manager and RA who will present materials and matters for discussion to the group and otherwise act as observers. The PPI group will be co-chaired by Burke from our PPI partner organisation (Foundation for People with Learning Disabilities) and one of the PPI group members with ID. The PPI group will also work with the research team in adapting the CSRI, developing the new stigma resistance measure and will advise on information sheets, consent forms and other study materials, will co-produce dissemination outputs for people with ID, act as ambassadors for the research project, and create communication pathways with organisations for people with ID. The group will also offer strategic advice on engaging organisations and participants, and will contribute to the interpretation of the study's findings and their dissemination. A separate PPI group of experienced group facilitators from the third sector and

education providers who are familiar with the STORM programme through participation in the pilot study will be established and meet at least six times during the study. This group will be co-chaired by the CI and Study Manager and will provide input on plans for recruitment, study materials and procedures, and will create communication pathways with organisations for people with ID.

23 Quality Control and Assurance

23.1 Monitoring

The clinical study risk assessment has been used to determine the intensity and focus of central and on-site monitoring activity in the STORM study. Low+ monitoring levels will be employed and are fully documented in the study monitoring plan.

Investigators should agree to allow study related monitoring, including audits and regulatory inspections, by providing direct access to source data/documents as required.

Findings generated from on-site and central monitoring will be shared with the Sponsor, CI and CTR.

23.2 Audits & inspections

The study may be participant to inspection and audit by UCL under their remit as Sponsor.

24 Publication policy

All publications and presentations relating to the study will be authorised by the SMG.

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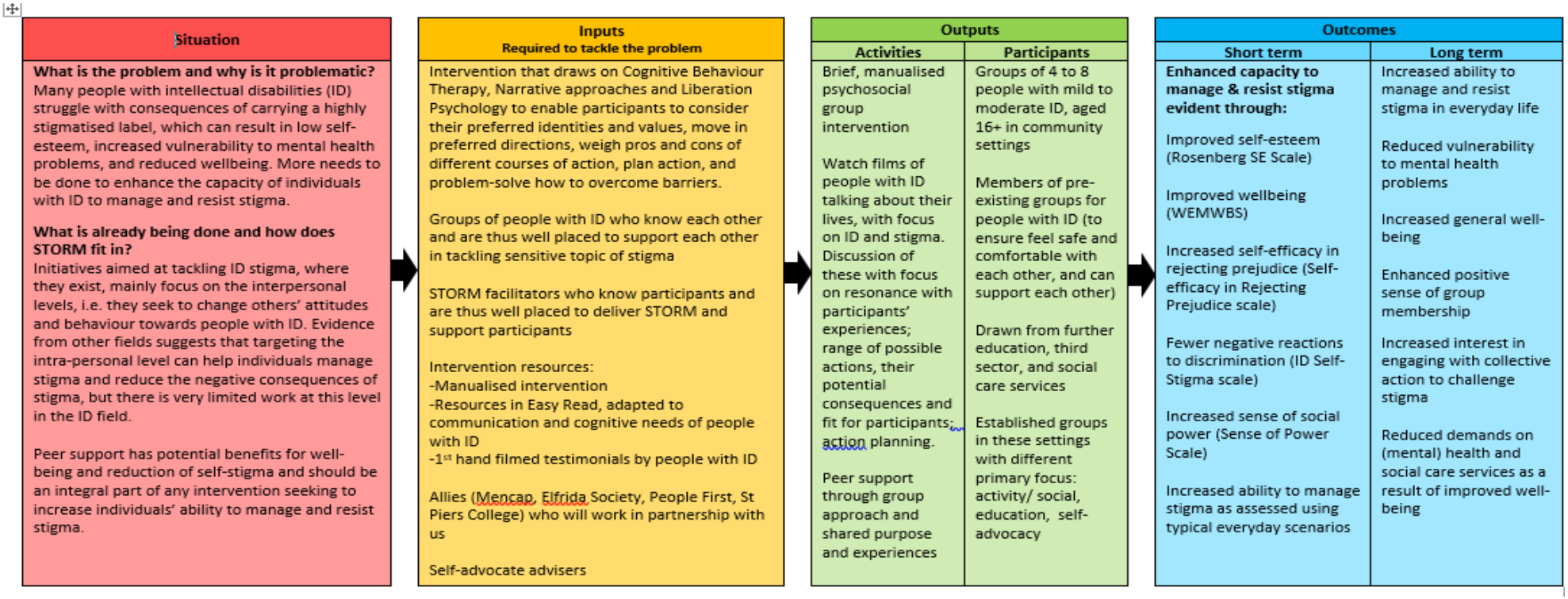
Appendix 1- STORM Logic Model



Assumptions
Individuals with ID are generally aware that they have an ID and that ID is stigmatised (confirmed by our Systematic Review [74]).
Awareness of negative connotations of ID label has negative effects on significant proportion of people with ID (confirmed by [74,75]).
For many, capacity to manage and resist stigma is low due to reduced cognitive and adaptive skills and disempowering environments.
Stigma resistance is associated with positive outcomes (confirmed by [19]).
Stigma management and resistance can be enhanced using psychosocial approaches in this population.
The same intervention will be suitable and effective for different subsections of people with mild to moderate ID aged 16+ and different settings.

External factors
Training and supervision for STORM group facilitators
Adherence to manual
Ready access to film-based materials, other resources, and equipment to show films (PC, laptop, or DVD player/TV)
Contextual variables (setting and group type)
Powerful external barriers reinforcing stigma and resisting development of new skills and more positive, empowered identity
Availability of opportunities to try out enhanced skills