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The standing up for myself (STORM) psychosocial group intervention for young people and adults with intellectual disabilities: Adaptation for digital delivery and pilot

Submission date
12/11/2019

Recruitment status
No longer recruiting

Registration date
18/03/2020

Overall study status
Completed

Last Edited
09/02/2024

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
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 tackle these social determinants of health, including efforts to reduce stigma (negative stereotypes, prejudice and discrimination).

Stigma has been linked to lower self-esteem, quality of life, and mental health problems, 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 group sessions and a follow-up 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.

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.

The widespread 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 wellbeing in this population, a priority in current health policy yet an area where people with ID have been largely excluded. 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.

The need for and importance of STORM to help people with ID to discuss negative experiences with their peers and resist stigma has been evident during the Covid-19 pandemic. 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.

Given current barriers to groups meeting F2F, adapting STORM so that it is suitable for digital delivery and, in future, could mean being able to offer alternative versions of STORM and thus allow more groups of people with ID to access STORM. It is also 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.

Who can participate?
Community and education sector organisations that work with groups of people with ID, and the people that attend them (aged 16 years or above).

What does the study involve?
Existing groups of people with ID will take part in a 5 session Digital STORM psychosocial intervention. They will participate from their own homes, using online meeting platforms such as Zoom and MS Teams. Prior to and following the intervention, participants will complete outcome measures via online meetings with a researcher. Following the intervention, groups will be invited to join a focus group to discuss their experiences and facilitators will be invited to take part in 1:1 interviews.

What are the possible benefits and risks of participating?
The possible benefits of participating are that participants may benefit from completing the Digital STORM programmme, they might learn something new from taking part and that the research may help other people with ID. Participants may find some questions and tasks difficult. In such instances, we will make sure that they can talk to someone.

Where is the study run from?
Research Department of Clinical, Educational and Health Psychology, University College London, UK

When is the study starting and how long is it expected to run for?
March 2020 to September 2021

Who is funding the study?
National Institute for Health Research (NIHR), UK

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

Central Portfolio Management System (CPMS)
45284

Protocol serial number
NIHR PHR 17/149/03

Study information

Scientific Title
The standing up for myself (STORM) psychosocial group intervention for young people and adults with intellectual disabilities: Adaptation for digital delivery and pilot

Acronym

STORM

Study objectives
Current study hypothesis as of 08/09/2021:
The aim is to adapt and pilot the existing STORM intervention for online delivery (Digital STORM, or STORM-e for short). Then to investigate the feasibility and acceptability of STORM-e, when delivered to groups of people with ID online. A further aim is to test digital administration of the study outcome measures and 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.

Previous study hypothesis:
The aim is to examine whether STORM can be delivered successfully to established groups of people with an intellectual disability (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. The study will assess 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)

Ethics approval required
Old ethics approval format

Ethics approval(s)
Current ethics approval as of 08/09/2021:
Approved 05/12/2019, amendment approved 22/01/2021, University College London Research Ethics Committee (Research Ethics Office, Office of the Vice-Provost (Research), University College London, 2 Taviton St, London WC1E 6BT; 020 7679 8717 extension 28717; ethics@ucl.ac.uk), ref: 0241/005

Previous ethics approval:
Approved 05/12/2019, University College London Research Ethics Committee (Research Ethics Office, Office of the Vice-Provost (Research), University College London, 2 Taviton St, London WC1E 6BT; 020 7679 8717 extension 28717; ethics@ucl.ac.uk), ref: 0241/005

Primary study design
Interventional

Study design
Intervention adaptation and pilot study

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Intellectual disabilities (learning disability)

Interventions
Current interventions as of 08/09/2021:
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 4 to 5 members. Facilitators will be

trained in delivery of the STORM-e intervention and provided with all of the necessary resources, furthermore, regular supervision will be made available from the intervention partner at Mencap. 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 trial.

Standing up for Myself (STORM), is a psychosocial group intervention. STORM works directly with groups of young people and adults with intellectual disability (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 follow-up 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, e.g. challenging negative beliefs and examining the benefits and disadvantages of different ways of responding to stigma; narrative therapy, e.g. by separating oneself from a problematised label and developing new stories about oneself; and liberation psychology, e.g. by explicitly acknowledging acts of oppression.

Total duration of treatment and follow-up is 2 months: 2 months for the intervention (4 weeks for the 4 core sessions plus a follow-up session one month after session 4)

Previous interventions:
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 (average cluster size) for the trial. 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 treatment as usual + 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 trial.

Standing up for Myself (STORM), is a psychosocial group intervention. STORM works directly with groups of young people and adults with intellectual disability (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, e.g. challenging negative beliefs and examining the benefits and disadvantages of different ways of responding to stigma; narrative therapy, e.g. by separating oneself from a problematised label and developing new stories about oneself; and liberation psychology, e.g. by explicitly acknowledging acts of oppression.

Total duration of treatment and follow-up is 12 months : 2 months for the intervention (4 months for the 4 core sessions plus a booster session one month after session 4) and 12 months from baseline for follow-up assessments.

Intervention Type
Other

Primary outcome(s)
Current primary outcome measure as of 08/09/2021:
Feasibility and acceptability of STORM-e will be addressed using a qualitative/quantitative (mixed-methods) evaluation of the following:
1. Recruitment of providers of groups for people with ID and of group facilitators: Can sufficient providers and group facilitators be recruited to run 4 STORM-e groups? Can sufficient group facilitators be recruited and trained?
2. Recruitment of participants/groups: Can sufficient participants with ID from a range of settings (educational, social/activity based, or self-advocacy groups) be recruited for the pilot?
3. Adherence: What proportion of groups and participants complete at least three of the five STORM-e sessions?
4. Retention: What proportion of groups and participants are retained in the study to post intervention?
5. Fidelity of implementation: Can facilitators deliver STORM-e with a high degree of fidelity to the programme manual?
6. Acceptability: Is STORM-e acceptable to facilitators and group members?
7. Usual practice (UP): What does UP consist of for young people and adults with mild to moderate ID? How is UP different since the pandemic, with groups meeting online?
8. Feasibility and acceptability of outcome measures: Do participants complete the outcome measures for the study? Do they find the outcome measures acceptable for people with ID to complete?
8. 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?
9. 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?
10. Acceptability of research design: Are organisations, facilitators and participants willing to be randomised within the context of an RCT?
11. Adherence: What proportion of groups and participants complete at least three of the five STORM sessions?
12. Retention: What proportion of groups and participants are retained in the study to the 12-month post-randomisation follow-up? Does retention differ between trial arms?
13. 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)?
14. 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?
15. Feasibility of outcome measures: Do participants complete the outcome measures for the study? Is there preliminary evidence of differences on these measures between the trial arms?
16. 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?
17. 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.

Previous primary outcome measure:
Feasibility will be addressed using a qualitative/quantitative (mixed-methods) evaluation of the following at 12-months:
1. Recruitment of providers of groups for people with ID and of group facilitators: Can sufficient providers and group facilitators be recruited to run up to 10 STORM groups and have 10 groups in the control arm? What factors influence providers' willingness to take part in the research? Can sufficient group facilitators be recruited and trained?
2. 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?
3. Acceptability of research design: Are organisations, facilitators and participants willing to be randomised within the context of an RCT?
4. Adherence: What proportion of groups and participants complete at least three of the five STORM sessions?
5. Retention: What proportion of groups and participants are retained in the study to the 12-month post-randomisation follow-up? Does retention differ between trial arms?
6. 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)?
7. 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?
8. Feasibility of outcome measures: Do participants complete the outcome measures for the study? Is there preliminary evidence of differences on these measures between the trial arms?
9. 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?
10. 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.

Key secondary outcome(s)

Current secondary outcome measures as of 08/09/2021:
Measured at baseline and post-intervention:
1. Mental wellbeing measured using the Warwick-Edinburgh Mental Well-Being Scale (WEMWBS), 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
2. Self-esteem, measured using 6-item version of Rosenberg self-esteem scale (RSES), validated for people with ID
3. Self-Efficacy in Rejecting Prejudice (SERP), a 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')
4. Reactions to Discrimination (RtD) 4-item subscale of the ID Self-Stigma Scale, measuring emotional reactions to stigma in people with ID

5. Sense of Social Power (SSP): adapted 4-item version of the Sense of Power Scale, to date not yet validated for people with ID
All the above scales use 3 to 5-point Likert response scales.

6. We aim to develop a measure of stigma resistance that is sensitive to change and will pilot this during the proposed study. For this purpose, 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 STORM Expert Advisors Panel, a Patient and Public Involvement (PPI) group.

Previous secondary outcome measures:
Measured at baseline and follow-up:
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Completion date
30/09/2021

Eligibility

Key inclusion criteria
Current participant inclusion criteria as of 08/09/2021:
Groups/organisations:
1. In place already (although group meetings may have been disrupted due to the COVID-19 pandemic and associated social restrictions)
2. Intend to continue or restart meeting as a group for ≥3 further months
3. ≥3 but ≤8 members with ID who wish to participate in the intervention
4. Willing to replace 5 of their usual meetings with STORM
5. Have a group facilitator who consents to taking part and who is willing to facilitate the STORM

intervention
6. The facilitator is willing to receive training and facilitate the STORM intervention and protocol in either face-to-face or digital form
7. Organisational support to deliver the study intervention

Individuals:
1. Aged ≥16 years
2. Have an ID as defined by an administrative definition
3. A member of an established group for people with ID (educational, activity, social, or self-advocacy focused)
4. Able to complete the outcome measures (with or without support) and engage with the STORM intervention
5. Have access to the internet and a device that can access web meetings, be this via Zoom, Skype, Microsoft Teams, or Google Meet, and where needed, have support to access web based meetings
6. Have capacity to provide informed consent to participation in the study
7. Able to communicate in English

Previous participant inclusion criteria:
For groups/organisations:
1. In place already, i.e. they are not specifically formed for the purposes of the intervention or the research
2. Intend to continue meeting as a group for at least three further months
3. 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
4. Willing to replace five of their usual meetings with STORM for the study
5. Have a group facilitator who consents to taking part and who is willing to facilitate the STORM intervention
6. 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
7. 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
8. 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

For individuals:
1. Aged 16+ years
2. 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
3. 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)
4. Have sufficient expressive and receptive communication skills in English (reading skills not required) to allow participation in STORM and completion of measures
5. Be a member of an established group for people with ID (educational, activity, social or self-advocacy focused)
6. Have capacity to provide informed consent to participation in the study
7. Provide informed consent to taking part in the study
8. 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 an assessment concludes that the potential benefits of taking part outweigh any risks and that participation in STORM is in the person's best interests

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

Total final enrolment
22

Key exclusion criteria
Current participant exclusion criteria as of 08/09/2021:
Groups/organisations:
1. Run as part of NHS services
2. 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

Individuals:
Do not provide consent to participate

Previous participant exclusion criteria:
For groups/organisations:
1. Run as part of NHS services
2. Some of their regular members decline taking part in STORM and it is not possible to find alternative meeting times to run STORM

For individuals:
1. Unable to communicate using English (and adaptations to meet their communication needs cannot be put in place for the respective group)
2. Do not have capacity to consent (see above)

Date of first enrolment
01/02/2021

Date of final enrolment
30/03/2021

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University College London
Research Department of Clinical, Educational and Health Psychology
1-19 Torrington Place
London
United Kingdom
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Sponsor information

Organisation
University College London

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		31/01/2024	09/02/2024	Yes	No
Results article		22/04/2023	09/02/2024	Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes