Manchester Metropolitan
University

Minority Interest

Minority Interest: Working to improve the cultural competency of supported living and residential care for adults with learning disabilities from minority ethnic communities

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Protocol authorised by:

Full name in print Role	Date	Signature
Prof Chris Hatton	22nd April 2025	

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Sponsor

Manchester Metropolitan University is the main research Sponsor for this study. For further information regarding the sponsorship conditions, please contact:

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Funder: NIHR Ref: NIHR206547

This protocol describes the Minority Interest study and provides information about procedures for entering participants. Every care was taken in its drafting, but corrections or amendments may be necessary. These will be circulated to investigators in the study. Problems relating to this study should be referred, in the first instance, to the Chief Investigator.

This study will adhere to the principles outlined in the NHS Research Governance Framework for Health and Social Care (2nd edition). It will be conducted in compliance with the protocol, the Data Protection Act and other regulatory requirements as appropriate.

Contents

1. BACKGROUND

There are no reliable statistics on the number of adults with learning disabilities from minority ethnic communities using social care in England, although the size of these groups is projected to rise substantially[1] . Sparse recent research[2] and the experience of Changing Our Lives from 20+ years working with people with learning disabilities from these communities[3] find they often experience poorer outcomes in relation to care and support and experience greater inequalities in relation to rights and personal freedoms. For instance, 'Small Margins'[3] a recent study focussing on the experiences of people with learning disabilities and autistic people from minority ethnic communities, showed people to have poor life experiences because of a lack of cultural competence in the social care workforce[4] across a whole range of aspects of people's lives, including religion, clothes and the way people want to look, food and drink, and connections in local communities. Social care workers varied in the extent to which they wanted to learn about the multiple facets of the person and what this meant for how people wanted to be supported, and rarely actively challenged the combinations of racism and ableism the person could encounter. The Small Margins report also identified a failure of services to recognise the intersectionalities that the whole person brings[5]. Similar issues have been consistently reported for over 30 years[6] .

There is increasing recognition of the pervasive inequalities experienced by people with learning disabilities from minority ethnic communities, including a review of health inequalities commissioned by the NHS Race & Health Observatory [4,7] and recent Care Quality Commission guidance [8] on the importance of culturally competent care (cultural awareness, knowledge, skills and motivation). Nevertheless, current support for providers/commissioners to improve their competence in this respect is sparse.

This study responds to this gap with the aim of producing evidence-based resources to improve the cultural competency of supported living and residential care services supporting people with learning disabilities from minority ethnic communities, while respecting the intersectionality of people's experience. The study will include people with lived experience in the research team and employ methods sensitive to the complexities of people's intersectional experience to explore experiences of social care support and the cultural competence of the services used by people across a range of ethnic minority communities. An action learning programme will be co-designed and co-delivered with people with lived experience, and evaluated in collaboration with service providers to maximise the chances of developing useful resources that will be feasible to use in routine practice.

2. RESEARCH QUESTION(S) AND OBJECTIVES

The overall aim of the project is to produce evidence-based resources to improve the cultural competency of supported living and residential care services, and residential respite care, supporting adults with learning disabilities from minority ethnic communities, while respecting the intersectionality of people's experience.

In terms of objectives, this research will work with: 1) adults with learning disabilities and their families from South Asian, Black African and African Caribbean communities living in supported living or residential care, including people with dual heritage; 2) managers/staff in provider organisations; 3) local authority commissioners to:

i. Explore what cultural competency means to people with learning disabilities and support staff and how this impacts on their support.

ii. Identify key barriers/success factors in the delivery of culturally competent services and collate examples of culturally competent service support.

iii. Examine how the intersection of ethnicity and disability impacts on people's lives and either shapes, or is ignored by, people's support.

From this learning, the project will:

iv. Co-design action learning training for staff in supported living, residential care and residential respite care, supporting people with learning disabilities to pilot and evaluate this action learning in practice.

v. v. Co-produce learning resources aimed at both providers and commissioners, examining the importance and impact of culturally competent services and how to achieve these. The resources could be available in easy read and other accessible formats so people with learning disabilities can be better informed and able to challenge.

Please note this protocol only addresses parts i-iii above. A separate protocol and ethics application will be made for parts iv-v.

3. RESEARCH DESIGN

There are six parts to the research in this protocol:

1) A rapid review of existing literature

2) Quality checks, undertaken by the research team including people with learning disabilities, to understand cultural competency in the lives of adults with learning disabilities from minority ethnic communities.

3) Data collection workshops with people with learning disabilities from minority ethnic communities

4) Data collection workshops with local authority social car commissioners

5) Data collection workshops with staff supporting adults with learning disabilities including people from minority ethnic communities.

6) Interviews with members of staff responsible for Equality, Diversity and Inclusion in organisations providing support to adults with learning disabilities, including people from minority ethnic communities.

Changing our Lives are leading and conducting the data collection. They will be employing people with lived experience as Quality Checkers to work alongside existing Changing our Lives staff.

A project advisory group comprising of key stakeholders will provide advice throughout the project.

Analysis

Data will be analysed using Framework Analysis. The framework will be developed using the findings from the rapid review alongside data collected from the first few Quality Checks and workshops and with input from the project's advisory group.

It is envisaged that the Framework Analysis will draw out key factors in the provision of culturally competent services that respect intersectionality, and barriers to culturally competent support. Examples of cultural competence present within the data will be collated for potential use in the action learning and project outputs. Both Manchester Metropolitan University and Changing our Lives will contribute to the analysis.

4. SETTING

Changing our Lives are coordinating and conducting all data collection. Their address is: Changing our Lives, C/O Irwin Michell, Riverside East, 2 Millsands, Sheffield, S3 8DT.

Data collection will take place in person at multiple locations throughout England. There is also a small amount of data collection which will occur online. The locations of the different procedures are as follows:

Quality Checks:

Quality Checks will take place in participants' homes (which will be supported living homes, residential care homes or a residential respite homes).

Workshops:

The workshops will take place in a community venue close to where the workshop participants are located, or in a venue connected to the organization participants are recruited from. The decision about which venues will be used for the workshop will be made by the research team and will take into consideration the location of the venue, the size of the venue and the suitability of it for participants' accessibility needs.

Interviews:

Interviews will take place online via MS Teams.

5. PARTICIPANTS

Participants will be distributed as follows:

Quality checks:

- 35-40 quality checks will take place with 35-40 participants with learning disabilities.

Workshops

- 6 workshops will take place with people with learning disabilities with 3-5 participants per workshop
- 6 workshops will take place with staff members from support provider organisations with 7-10 participants per workshop
- 3 workshops will take place with relevant local authority commissioning staff with 6-10 participants per workshops

Interviews:

- 6 interviews will take place with support provider EDI leads or people in functionally equivalent roles

5.1. Inclusion Criteria

Please note, as the focus is on services for adults with learning disabilities, all participants will be aged 18 and over.

Quality Checks:

- People with learning disabilities who are aged 18 and are from South Asian, Black African and African Caribbean communities, including people with dual heritage.

  And

- Living in a supported living or residential care home or regularly using residential respite care with support provided by one of the organisations supporting the project with recruitment (See recruitment section).

- Workshops: People who have a learning disability who are aged 18+, living in England, and from an ethnic minority community.

  Or,

- People who are employed as support staff at one of the provider organsiations supporting the study with recruitment.

  Or,

- People who are local authority commissioners working in roles relevant to learning disability services and employed by one of the local authorities supporting the study with recruitment.

Interviews: People who are employed by one of the provider organisations supporting the study with recruitment and are considered the organisation's EDI lead, or are in a functionally equivalent role.

5.2. Exclusion criteria

Quality Checks:

- People who are under the age of 18

- People who do not consent to take part or, if they lack capacity to consent, a nominated or personal consultee does not agree to their participation.
- People involved in ongoing legal proceedings involving health and social care services.

Workshops:

- People who are under the age of 18
- People who do not consent to take part or do not have capacity to consent to take part.
- For the workshops with commissioners, people who do not have a relevant role
- People involved in ongoing legal proceedings involving health and social care services.

Interviews:

- People who do not consent to take part
- People who do not have a relevant job (EDI Lead or functionally similar role)

6. STUDY PROCEDURES

6.1. Participant Recruitment

There are 6-8 provider organisations and 3 local authorities supporting the research with recruitment. All participants, bar those participating in the learning disability workshops, will be recruited through these organisations via purposive sampling to ensure a spread of participants. Due to the nature of the research, and the potential for participants to share sensitive information about the organisations during data collection, the provider organisations and local authorities are remaining anonymous.

The recruitment processes for the different parts of the project are explained in detail below:

a) Quality checks

- The supporting provider organisations will identify suitable participants for the research from the people they support.
- The provider will share the participant information sheet, consent form and a short YouTube video with the people they have identified in the language right for them. Recruitment materials for participants with learning disabilities are adapted to ensure they are accessible. Information sheets and consent forms are in easy read formats

(which involves simplified text and accompanying pictures) and there is a short YouTube video to explain the research. All forms can be translated into a different language as required. While the video contains instructions on how to change the subtitle language, if the information sheets and consent forms are required in a different language, the provider will inform the research team who will then arrange for the documents to be translated ensuring the provider can distribute the appropriate documents

- Once people have had time to consider the research (between 24 and 48 hours), if they are interested in participating, the provider will ask for their consent to share their contact details with the research team at Changing our Lives and will support the participant to complete a consent to contact form which will be passed on to Changing our Lives.
- Changing our Lives will then get in touch with the participant/and or their support staff (where appropriate) to explain the research in more detail, establish what the participant's support needs are (for example, how they communicate) and arrange a time to visit them at their home to begin the Quality Check. NB, as part of the initial conversations, Changing our Lives will also ask if ask if participants (or consultees) are happy for a family member to be involved in the Quality Check (more information about this is provided in the consent section below).

For people who would not be able to consent to take part in the research themselves (as determined by a person in the supporting provider organisation who knows the potential participant well), the provider organisation will approach the person's legal representative (such as an attorney or deputy appointed by the Court of Protection). If there is no legal representative, they will approach a close family member to share information about the research to see if they would be willing to act as a Personal Consultee. If there is no personal legal representative or close family involved, they will instead approach a member of staff who knows the person well and works closely with them (e.g. their keyworker or home manager) to request they act as a Nominated Consultee. This process is in line with the Mental Capacity Act guidance.[9]

The team at Changing our Lives will record participant demographic information to ensure a spread of participants (age, gender, ethnicity) and living situations (supported living, residential care, residential respite care) are included.

b) Workshops

I. **With people with learning disabilities.** Changing our Lives will contact existing networks of people with learning disabilities from ethnic minority communities to discuss the research and share the participant information sheets. If a group/network is interested in taking part in the research, Changing our Lives will liaise with the group to find a suitable time and location for the workshop which members of the group/network will be invited to attend. The information sheet contains contact details for Changing our Lives so potential participants can get in touch if they would like to know more information or have any questions prior to the workshop.

II. **With support staff:** Changing our Lives will liaise with the supporting provider organisations to arrange a suitable time and location for the workshop. The provider organisation will share details of the research with support staff working within their organization (participant information sheet and consent form) and invite them to participate in the workshop. The information sheet contains contact details for Changing our Lives so potential participants can get in touch if they would like more information or have any questions prior to the workshop.

III. **With local authority commissioners:** As with support staff above, Changing our Lives will liaise with the local authorities to arrange a suitable time and location of the workshop. The local authority will then pass on information sheets and consent forms to potential participants and invite those who are interested to attend the workshop. can get in touch if they would like more information or have any questions.

c. **Interviews**. The core participating provider organisations will share information about the research with members of their staff who meet the eligibility criteria. Once people have had time to consider participation (between 24 and 48 hours), those who are interested in taking part, will be asked to complete a Consent to Contact from which the provider will then pass on to the research team at Changing our Lives. A member of the research team will then get in touch with the interested participants to confirm eligibility, arrange a time for the interview and explain the consent process.

6.2. Consent

Consent will be obtained in different ways depending on the participant group and method. The different processes are outlined below:

a. Quality checks

The quality checks will include participants who are able to consent for themselves as well as some people who do not have capacity to consent to take part in the research (as determined by the provider). Informed consent will be obtained directly from all participants who can consent. For those who can't, a consultee process will be followed.

For participants who can consent for themselves the process will be as follows:

- As part of the recruitment process, the provider will have discussed the research with potential participants with the help of the information sheet and video.
- Once the person has had time to think about the research (between 24 and 48 hours), if they are interested in taking part, they will complete the consent to contact form and the provider will pass this on to the research team at Changing our Lives.
- Changing our Lives will get in touch with the participant/and or their support staff (where appropriate) to explain the research in more detail, establish what the participant's support needs are (for example, how they communicate) and arrange a time to visit them at their home to begin the Quality Check.
- At the start of the Quality Check, the researchers will read through the consent form with the participant and answer any questions they may have. It will be emphasised that they do not have to participate if they do not wish to, that their decision will not affect the care and support they receive and that they are free to drop out of the research up to the point of analysis. If the person is happy to proceed, the participant will be asked to sign the consent form.

NB, If a participant is unable to provide written consent, verbal consent will be taken. This will be recorded, with the researcher asking the participant to confirm their name before reading the consent form out loud (including version number and date of consent form). The researcher will pause after each item on the consent form to allow the participant to audibly confirm for the recording.

As part of the initial conversation with participants, Changing our Lives will ask participants if they are happy for their families to be contacted and involved in the Quality Check. If this is relevant and participants agree, the support provider will contact the family member for permission to pass on their contact details to Changing our Lives. Changing our Lives will then contact the family member and provide them with a participant information sheet and consent form which they will be required to sign and give back to the research team.

For participants who do not have capacity to consent for themselves (as determined by the provider) the process will be as follows:

- The provider will contact an appropriate personal or nominated consultee. This will be a personal legal representative, such as an attorney or deputy appointed by the Court of Protection, or if the person does not have a legal representative, a close family member (personal consultee). If there is no legal representative and no family involved in the person's life, the consultee can be a close member of staff (nominated consultee). The consultee will be given information about the research, the role of a consultee, and a consent form, and if they are willing to act as a consultee, they will be asked to complete a consent to contact form. The provider will then pass on the consent to contact form to the research team at Changing our Lives.
- Changing our Lives will contact the consultee and explain the research, and the role of the consultee in more detail. If, having read and considered the information, they are happy to act as a consultee and for the person to take part, they will be asked to sign and return the consultee consent form. The research team will liaise with support staff to arrange a time for the Quality Check.
- The personal consultee consent form will also ask if the consultee consents to be involved in the Quality Check as a family member.
- NB, Quality Check visits with participants included through the consultee process, will only go ahead as long as there is **assent** from the participants, and the participants appear comfortable with the researchers being present. Changing our Lives staff are experienced at working with people with a severe or a profound and multiple learning disability who would not be able to consent to take part in the research. They will work closely with the consultee and the support staff who know the person best to ensure the research team understands how the person would

communicate that they assent and are comfortable for the researchers to spend time in their home with them. Conversely the researchers will ensure they understand how the participants would communicate that they are unhappy. Alternative methods of communicating that the visit and research are about their culture and ethnicity to participants will be considered such as sensory communication, smells of food, visual and tactile stimuli such as fabrics as well as music and other media may be used.

Ongoing consent and assent: Consent and assent are viewed as ongoing processes and not something only established at the start of the research. Therefore, the researcher will pay attention to both verbal and non-verbal signals from all participants throughout the Quality Check (including those taking part via the consultee process). If the participant appears uncomfortable at any point the researcher will check if they are ok and whether they wish to continue (and/or will check with the participant's support worker where appropriate). As the quality check may be spread over several days, the researchers carrying out the Quality Check will check in with participants (and where appropriate support staff) at the start of each session to check that they are happy to continue. They will also check in with the house, as a whole, to ensure it is appropriate for the visit to go ahead.

b. Workshops: All participants will have capacity to consent to the research and will have been provided with a participant information sheet and consent form prior to the workshop taking place and will have had at least 48 hours to consider their participation. At the start of the workshop the researcher will run through the information about the research and the items on the consent form, including the right to withdraw and participants will have a chance to ask any questions. Participants will then be asked to sign their consent forms before the workshop commences. If participants are unable to give written consent, verbal consent will be taken in the same manner as outlined in the Quality Checks consent process.

c. Interviews:

Once changing our lives have received the consent to contact forms from the provider organisations they will contact participants to discuss the research further and answer any questions participants have. If the person is still happy to take part following this conversation, Changing our Lives will arrange a time for the interview with the participant. Changing our Lives will then request that participants complete the consent form and return it to them via email prior to the interview. At the start of the interview, the researcher will

run through the consent form again and reiterate that the participant is free to withdraw up to the point of data analysis. The researcher will check that the participant is happy to proceed before commencing the interview.

6.3. Withdrawal Criteria

All participants can withdraw from the research at any point and without giving a reason. Participants can have their data removed from the project up until one month after the date of the interview, workshop, or their last Quality Check visit.

Alongside information about withdrawal within the information sheets, all participants will be reminded verbally at the start of the quality checks, workshops, and interviews that withdrawal from the study is possible prior to data analysis taking place. To withdraw, participants (or someone supporting them) would contact a member of the research team and inform them of their decision which could include the removal of all or partial data. A record of the withdrawal, and what data has been destroyed in connection to the withdrawal, will be made in line with Manchester Metropolitan University's Guidance.

7. INCIDENTS

Definitions:

Adverse Event (AE): any untoward medical occurrence in a patient or clinical study subject.

Serious Adverse Event (SAE): any untoward and unexpected medical occurrence or effect that:

1 Results in death

2 Is life-threatening – refers to an event in which the subject was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe

3 Requires hospitalisation, or prolongation of existing inpatients' hospitalisation

4 Results in persistent or significant disability or incapacity

5 Is a congenital anomaly or birth defect

Serious Adverse Events are not expected to occur due to any of the procedures in this project. However, it is possible that a SAE could occur in the normal care routine of the participant, unrelated to this project. In the unlikely event that such a SAE occurs and it affects the patient's ability to continue participating in the project, a SAE form will be completed and shared with the Chief Investigator within 24 hours. The Chief Investigator will notify the Sponsor, will withdraw the participant from the project, and the report will be kept in the study master file.

Any adverse events which occur, but do not count as an SAE, will also be reported to the Chief Investigator and a record kept in the study master file.

The name and e-mail and postal addresses for the Sponsor is provided for participants on the information sheets as the independent contact for concerns or complaints. This is Dr Ramona Statache, Research Ethics and Governance Manager, Manchester Metropolitan University, 6-8 Great Marlborough Street, 2nd Floor, Research & Innovation Directorate, Manchester, M1 5AL, UK, ethics@mmu.ac.uk .

8. DATA ANALYSIS AND HANDLING

The following data will be generated:

From participants:

- Personal identifiable information: names, contact details and demographic information, Names and contact details will be recorded in a spreadsheet while demographic information (age, gender, region, ethnicity, living situation and whether or not they have a profound and multiple learning disability) will be recorded via a demographic monitoring form.
- Consent to contact forms (containing participant names and contact details)
- Consent forms (including electronic forms, hard copies and audio recordings where participants have given verbal consent)

From the Quality Checks:

- Hand-written or typed field notes and Quality Check summaries

From the workshops:

- Hand-written or typed field notes

From the interviews:

- Video recordings of the interviews

- Interview transcripts

8.1. Sample Size

Sample sizes in qualitative research are commonly between 15-30 with 50 considered to be a large sample (Braun and Clarke, 2013). However, in order to carry out both the Quality Checks and workshops with people from different stakeholder groups we will recruit a large sample consisting in total of:

- Between 53 and 70 adults (18 and over) with learning disabilities who are from an ethnic minority community or who have dual heritage.
- Between 42 and 60 staff members who provide support to people with learning disabilities within the participating support provider organisations.
- Between 18 and 30 local authority commissioners.
- 6 EDI leads (or people in a functionally similar role) from within the participating support provider organisations.

8.2. Data Collection

Quality checks

Between 35 and 40 Quality checks will be conducted by Changing our Lives over nine months in 2025. Each check will be carried out by a member of the core research team and a trained 'Quality Checker' who is a person with learning disabilities employed by Changing our Lives. They will spend up to 2 days per person with the individual. A range of tools may be used during the quality check depending on the participant and their circumstances.

- Spending time with individuals and 'walking through' their life, getting to know them and asking them a series of questions around cultural competency and the way they are being supported in relation to this,
- Meeting with the person's family (wither online, by telephone or in person) to discuss cultural competency and their views on the way their relative is supported in relation to this.
- Asking staff to volunteer comments anonymously to help the Quality Checkers assess the environment and the situation.

- Observation of practice with a focus on cultural competency between professionals/staff and people they work with,
- Checking people's plans e.g. person-centred plans, communication passports and other documents for best practice,

Quality Checks will be carried out flexibly and at the participants' pace, with the researchers responsive to the fluctuating needs of individuals. Therefore, the sessions can be broken up into shorter visits or the researchers can leave and return at a different time should the participant wish. When planning the visits, the researchers will work closely with the individual and the provider to ensure consideration is given to what else may be going on in the house at the same time.

The Quality Checks will be recorded via detailed field notes hand-written over the 2 days and collated into a standard template as soon as possible after the Check. Quality Checks have been selected for this project as they are more sensitive to the intersectional complexities of people's lives than standardised questions. This methodology has been successfully used in a previous, related project, funded by the NIHR and approved by the Social Care REC.[10]

Workshops

Workshops will take place face-to-face and they will be held in the local areas where participants are recruited using accessible community spaces or provider or council meeting rooms. The workshops will last approximately 3 hours and be facilitated by Changing our Lives. Information from workshops will be recorded via handwritten notes, and key points agreed by the groups as well as areas of non-consensus. Participants with learning disabilities will be paid for their participation in line with the Involve rates. It is expected that the workshops with local authority staff and provider organization staff will take place during their usual working hours, with the agreement of their employer, and therefore they will not be remunerated for their time.

Interviews

Semi-structured interviews will take place with 6 EDI leads from the supporting provider organisations. Interviews will be conducted by a member of the research team from Changing our Lives and will take place online Via MS Teams and will examine how their policy and practice are embedded within cultural competency. Participants will be emailed a link and passcode to the Teams meeting and this will not be shared with anyone else. The interviews will be recorded and transcribed using the inbuilt recording software available with Teams. Interviews will last up to 120 minutes.

8.3. Data Handling

As the project is a collaborative one between three separate organisations (MMU, Changing our Lives and the National Development Team for Inclusion), DropBox for Business will be used to share data during the project and allow for collaboration. A collaboration agreement is in place between MMU, Changing our Lives and the National Development Team for Inclusion and has been approved by the funder. As far as possible data will be anonymized by Changing our Lives prior to transferring to Dropbox. Data which does not require ongoing collaboration will be removed from Dropbox for Business as soon as practically possible and held on the university's permanent RDS platform. RDS is the university's secure research data storage solution with data backed up through instant replication and disaster recovery options to prevent data loss.

Below the data handling process for the different data sets is outlined:

<u>Data generated from participants:</u>

Participants' names and contact details will be recorded in a password protected spreadsheet kept by Changing our Lives in a folder on their secure server. The spreadsheet will be kept for up to 12 months after the end of the project to allow for the sharing of findings with participants. A key to participants' names and ID numbers/pseudonyms will be kept separately from the participants' details in a password protected file.

Demographic monitoring form. Demographic information will be recorded in a spreadsheet using participants' ID number and Pseudonym. The form will be updated by Changing our Lives throughout the project and kept in Dropbox for Business to allow for collaboration. At the end of the project it will be transferred to the RDS platform.

<u>Consent to contact forms.</u>

Changing our Lives will receive the consent to contact forms from the provider organisations and local authorities supporting the research. Changing our Lives will add the participants' details to their participant spreadsheet and then upload the forms to Dropbox for Business. A member of the research team at Manchester Metropolitan University will then transfer the forms to the university's RDS platform where they will be kept for the duration of the project.

<u>Consent forms.</u>

Consent forms may be paper or electronic forms or take the form of an audio recording. Where paper forms are used, Changing our Lives will scan or take a photo of the form and upload it to Dropbox for Business and destroy the hard copy. Electronic forms and audio recordings will also be uploaded to Dropbox for Business along with the email accompanying the electronic form (where the consent form was received by email) and the original copy deleted. A member of the research team at Manchester Metropolitan University will remove the forms from Dropbox for Business and transfer them to the RDS platform.

Quality check data:

Changing our Lives will keep their field notes securely and will not leave them unattended in a public place or in their car. From the field notes they will type up a summary of the Quality Check and destroy their field notes. The summary will be psuedanoymised using the participant ID number or a pseudonym chosen by the participant and identifying information removed. The summaries will then be uploaded to Dropbox for Business to allow for collaborative analysis to take place. At the end of the project they will be transferred to the RDS platform.

Workshop data:

If not already typed, fieldnotes from the workshops will be typed up by Changing our Lives and the hard copies destroyed. Changing our Lives will ensure the notes are pseudoanonymized, and identifying information removed, before they are uploaded to Dropbox for Business where they will be shared to allow for collaborative analysis. At the end of the project they will be transferred to the RDS platform.

Interview data

Interview recordings will be downloaded from MS Teams after the interview and transferred to Dropbox for Business by Changing our Lives. Changing our Lives will then notify a member of the research team at Manchester Metropolitan University who will then transfer the recording from Dropbox for Business to the RDS platform. The original recording on Teams will be deleted once the recording and transcript have been transferred to Dropbox for Business.

Interview transcripts, generated through MS Teams inbuilt software will be downloaded as a Word Document. Changing our Lives will then pseudoanonymise the transcripts, using the participant ID number or pseudonym and removing identifying information, before transferring them to Dropbox for Business to allow for collaborative analysis to take place. At the end of the project they will be transferred to the RDS platform.

No personal data will be processed outside of the UK. No data will be stored on any local drives (e.g., computers, USB flash drives). Security, processing, and data protection in all institutions will be compliant with the GDPR and minimise exposure to risk.

8.4. Access to Data

Data access will be granted to authorised representatives from the Sponsor, host institution and the regulatory authorities to permit study-related monitoring, audits and inspections.

8.5. Archiving

Archiving of study documentation will be authorised by the sponsor following submission of the end of study report.

At the end of the project the Dropbox for Business account will be deleted and all data remaining here for collaborative purposes will be transferred to the RDS platform where it will be archived and stored for 10 years in line with Manchester Metropolitan University's retention and disposal schedule. This includes the consent forms, recordings, anonymised interview transcripts, anonymised field notes, and anonymised demographic information.

Personal identifiable data held by Changing our Lives (participant names, contact details and the key to the participant identification numbers) will be destroyed 12 months after the end of the project. This is to allow for the sharing of outputs and findings with participants.

8.6. Record Keeping

Data sharing agreements are in place between the three organisations running the project (Manchester Metropolitan University, Changing our Lives and the National Development Team for Inclusion). A study master file is in place and contains all project records including communication with the Sponsor, REC and funder.

9. REGULATORY ISSUES

9.1. Peer Review

This project is funded by the NIHR (NIHR206547). Extensive NIHR independent external review took place as part of the process of deciding to fund the project. The NIHR funding panel is a specific social care research panel, including academic social care expertise, experts by experience, and social care commissioners.

9.2. Ethics Approval

The Chief Investigator will obtain approval from the HRA and Manchester Metropolitan University. All correspondence with these organisations will be retained in the study master file.

Amendments will be forwarded to the Sponsor Amendments will not be implemented until the HRA have approved the amendment.

An annual progress report (APR) will be submitted to the REC within 30 days of the anniversary date on which the favourable opinion was given, and annually until the study is declared ended. The Chief Investigator will notify the REC of the end of the study, and if the study is ended prematurely, the Chief Investigator will notify the REC, including the reasons for the premature termination. Within one year after the end of the study, the Chief Investigator will submit a final report with the results, including any publications/abstracts, to the REC.

9.3. Insurance

Manchester Metropolitan University holds insurance that provides cover for harm arising from the design, conduct and management of the research.

9.4. Health and Safety

Risks to research participants:

Emotional well-being:

Participants will be recruited through provider organisations, local authorities and existing networks. This means that the organisations or the participant's employer will be aware of the research and would be able to offer informed support to any participants who require support following

involvement in the research. Where appropriate the research team will notify support staff, should a participant with learning disabilities become distressed during or after the research.

It is unlikely participants will be verbally or physically abusive. However, should this occur during a workshop there is a risk to the well-being of other participants. The abusive participant would be asked to leave and the researcher will check in with remaining participants to ensure they are ok. If the researcher had concerns for the safety of any of the participants, this would be reported to the relevant emergency service or to a contact within an organisation that provides support to the participant where appropriate.

In addition, the research team will have in place a safeguarding policy, adapted from one the team used with in previous related research (200 Lives).

Risks to Researchers/Interviewers:

Emotional well-being:

it is not envisaged that the research will be distressing for researchers. However, if it is challenging, researchers will take breaks after data collection and speak to other team members.

Threat and abuse:

It is unlikely a participant will make verbal threats or display abusive behaviours during data collection. However, should this happen the interview/quality check would be terminated or they would be asked to leave the workshop. The researcher would seek advice and support for themselves as necessary (e.g. speaking with colleagues, or the emergency services depending on what occurred). The level of risk is low.

Lone researchers – There may be limited lone working for researchers conducting the Quality Checks. However, where this does occur, the researcher will have previously met with the participant and visited them at their home and will be comfortable in conducting the visit alone. As it is Changing our Lives carrying out the data collection they will work in accordance to their Lone Working Policy.

Whilst interviews will also take place with one researcher, the researcher will have already met/spoken with the participant as part of the recruitment process and the interviews will take place online. Therefore, risks from lone working are expected to be minimal.

Including people with lived experience as researchers: Changing our Lives employ people with learning disabilities as part of their project research team to support with the Quality Checking and analysis. Changing our Lives are highly experienced in doing this and have a history of recruiting, managing and involving people with learning disabilities in research as paid staff members. Each Quality Check will be conducted by a Quality Checker with learning disabilities working alongside a core member of the research team.

9.5. Conflicting Interests or Competing Roles

None identified.

9.6. Monitoring, Audit & Inspections

The Sponsor monitors and routinely audits projects in its research portfolio.

9.7. Protocol Compliance

Protocol deviations can happen at any time. They must be adequately documented on the relevant forms and reported to the Chief Investigator and Sponsor Immediately.

Protocol deviations, non-compliance, or breaches are departures from the approved protocol and would therefore be unauthorised.

Deviations from the protocol that are found to frequently recur are not acceptable, will require immediate action and could potentially be classed as a serious breach.

A 'serious breach' is a breach which is likely to effect to a significant degree –

- The safety or physical or mental integrity of the subjects of the study; or
- The scientific value of the study.

The Sponsor will be notified immediately of any case where the above definition applies during the study conduct phase.

9.8. Amendments

The Chief Investigator will be responsible for overseeing any protocol amendments. All amendments will be tracked in the study master file and the version number updated accordingly on the amended protocol. It is the sponsor's responsibility to decide whether an amendment is substantial or non-substantial.

If the sponsor wishes to make a substantial amendment to the REC application or the supporting documents, the sponsor must submit a valid notice of amendment to the REC for consideration. The REC will provide a response regarding the amendment within 35 days of receipt of the notice. It is the sponsor's responsibility to decide whether an amendment is substantial or non-substantial for the purposes of submission to the REC.

Data Protection and Confidentiality

Manchester Metropolitan University and Changing our Lives are the Data Controllers for the project. Professor Chris Hatton, Chief Investigator is the Data Custodian at Manchester Metropolitan University and Lucy Dunstan, Co-investigator is the Data Custodian at Changing our Lives. They will ensure that the data is securely stored and managed as set out in this protocol.

To ensure data protection and confidentiality the following arrangements are in place:

- Participants will be allocated an ID number and will be asked to choose a pseudonym. This will then be used in place of their name throughout the project. The key to the pseudonyms and codes will be kept in a password protected file separate to participant contact details and other data on the Changing our Lives secure server.
- As far as possible all data will be anonymised or pseudoanonymised by Changing our Lives prior to sharing via Dropbox for Business.
- Access to data will be limited to the minimum number of individuals necessary for quality control, audit and analysis.
- The meeting invite and passcode for the Teams Interviews will only be shared with the relevant participant. The waiting room function will be enabled so the researcher can ensure they only allow the participant into the interview. At the end of the interview the recording and transcript will be shared via Dropbox for Business and deleted from Teams to prevent unauthorized access.
- Research outputs, including publications, will not contain any identifiable information.

In the case of a data breach, the first person to become aware of the data breach will immediately inform the project's Chief Investigator, Professor Chris Hatton, who will then inform the Data Protection Officer at Manchester Metropolitan University. This will enable the University to report any data breaches to the Information Commissioner's Office within 72 hours.

10. DISSEMINATION POLICY

The management of Intellectual Property Rights is set out in the collaboration agreement which is in place between, Manchester Metropolitan University, Changing our Lives and the National Development Team for Inclusion.

Changing Our Lives own the Background IP to the Quality Checks being used in the research project, and through a signed collaboration agreement have agreed that MMU can use the quality checks that they own for the duration of the project. Results and Foreground IP will be owned and controlled by Manchester Metropolitan University, except for specific resources as set out in the collaboration agreement which will be owned by Changing our Lives.

As detailed in section 9.2, an annual progress report (APR) will be submitted to the REC within 30 days of the anniversary date on which the favourable opinion was given, and annually until the study is declared ended. Within one year after the end of the study, the Chief Investigator will submit a final report with the results, including any publications/abstracts, to the REC.

Progress reports will also be submitted to the funder, NIHR, every 3 months using a standardised pro forma. A final report, also using a standardised pro forma, will be submitted within 14 days of the end of the project.

ResearchFish will be updated by the Chief Investigator, once a year during the project and for 5 years beyond the end of the project. We will also produce peer-reviewed journal article/s and other outputs which will be shared publicly via the Changing our Lives website, the National Development Team for Inclusion's website and the Learning Disability and Autism Research Group's website at Manchester Metropolitan University . Authorship will be determined on a case-by-case basis. In all instances the funder NIHR (NIHR206547) will be acknowledged.

Qualitative data arising from the project will not be made publicly available in open access repositories due to the potential for identification of individuals and provider organisations in individual Quality Check summaries, workshop data and interview transcripts even after anonymisation.

11. PROJECT TIMELINE

A detailed Gantt chart is included in the Appendix (13.1). The total length of the project is currently 34 months. This includes 16 months for stage one and the research activities detailed in this protocol and 18 months for stage two.

12. REFERENCES

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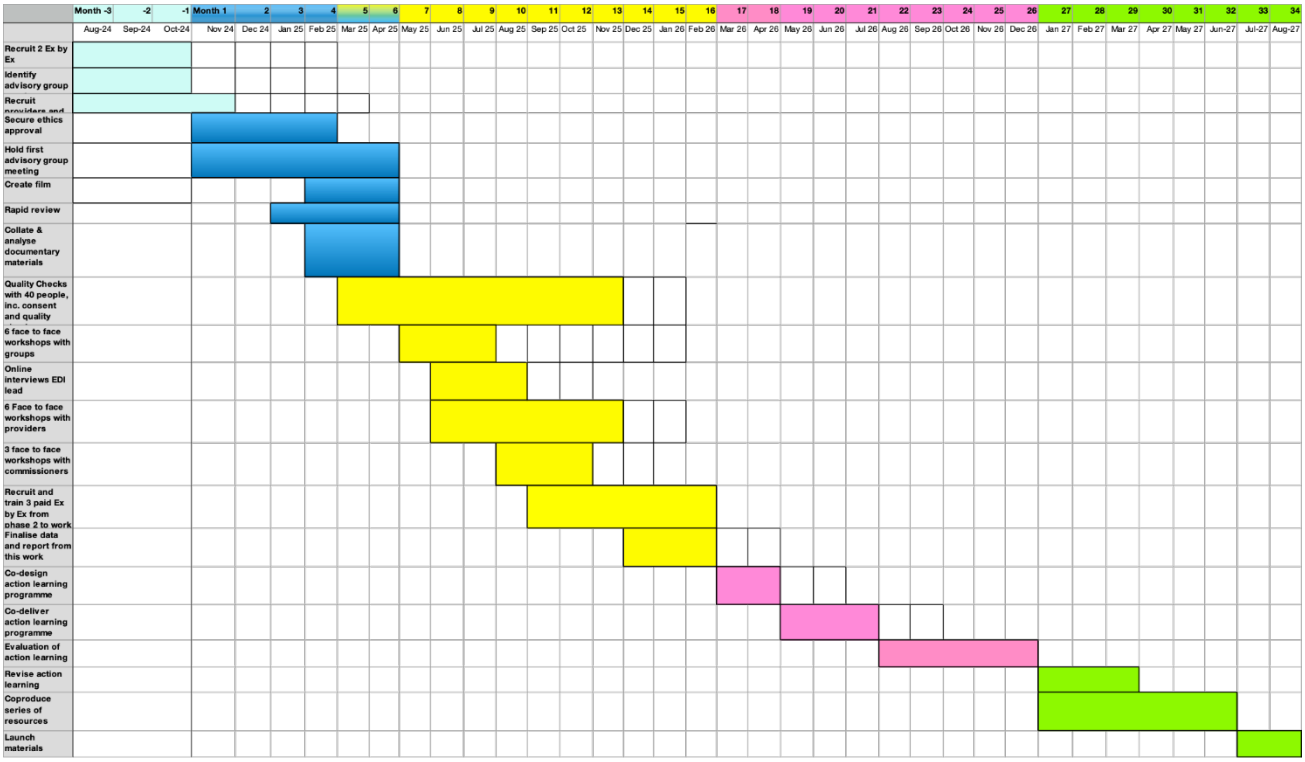
10. Hatton C, Ribenfors F, Blood L, Marriott A, Woodward E, Dunstan L, Nadat S, Taylor J, Knapp M, King D & Zhang K (2022). 200 Lives: Evaluating supported living and residential care for adults with learning disabilities. Bath: National Development Team for Inclusion. https://www.ndti.org.uk/assets/files/200-Lives-Fullreport.pdf

13. Appendix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Recruit 2 Ex by Ex
Identify advisory group
Recruit
Secure ethics approval
Hold first advisory group meeting
Create film
Rapid review
Collate & analyse documentary materials
Quality Checks with 40 people, inc. consent and quality
6 face to face workshops with groups
Online interviews EDI lead
6 Face to face workshops with providers
3 face to face workshops with commissioners
Recruit and train 3 paid Ex by Ex from phase 2 to work
Finalise data and report from this work
Co-design action learning programme
Co-deliver action learning programme
Evaluation of action learning
Revise action learning
Coproduce series of resources
Launch materials