# Improving the health, wellbeing and social networks by of older adults with intellectual disability: The Matilda Study

Submission date	<b>Recruitment status</b> No longer recruiting	[X] Prospectively registered		
02/12/2022		∐ Protocol		
Registration date	Overall study status Completed Condition category	Statistical analysis plan		
20/12/2022		Results		
Last Edited		Individual participant data		
01/02/2023	Mental and Behavioural Disorders	Record updated in last year		

#### Plain English summary of protocol

Background and study aims

Like the general population, the average age of people with intellectual disabilities is rising. However old age for people with intellectual disabilities is different. It starts earlier and has more impact on their physical and mental health. Most older adults with intellectual disabilities feel isolated and cut off from friends and local communities. But joining a local community group (such as men's sheds, dance, sports, and knitting groups) can help them feel less lonely or depressed and more included in society, and improves their quality of life.

A team of Australian researchers developed a social intervention called Transition to Retirement (TTR), a peer-led project. They trained 2-3 retired adults without disabilities who were part of a local community group to act as volunteers or mentors and to support an older person with an intellectual disability to take part in the group a few times a week for at least six months. The project helped older adults with intellectual disabilities to develop new social networks and friendships by working with peers who did not have a disability. They became more connected with their local communities and felt less lonely and isolated. The adults with intellectual disabilities liked the project and the mentors continued providing support even after its funding ended.

Recently, our team in Northern Ireland met with stakeholders to see if we could adapt the TTR project for the UK. There was less emphasis on retirement and more on supporting older adults with intellectual disabilities to become involved in their local communities. We changed the name to Matilda (Managing Activities Together, to involve older people with intellectual disabilities in their local community) and we're now ready to test if this can be delivered and is acceptable in the UK. The study aims to test whether Matilda can help older adults with intellectual disabilities participate in local community groups with the support of mentors without disabilities, to improve their health, well-being and social networks.

Who can participate?

Adults aged 45 years old and over with mild/moderate intellectual disability

What does the study involve?

This 30-month study will run in Northern Ireland and London. If an older adult with intellectual

disabilities and their carers agree to take part they will answer some questions about their health, well-being, social networks and the services they receive before being randomly (by chance) allocated to either the 6-month Matilda intervention or usual care (to provide a control group). Those allocated to the control arm will receive usual care and 3 recreational activities with their intellectual disability peers over the course of the study (cinema, bowling, meal). The adults with intellectual disabilities in both arms will complete the same questionnaires at baseline, and 6 and 12 months later. The mentors will also be asked to provide information at the same time points on their health, well-being and attitudes towards people with disabilities. Volunteer Now in Northern Ireland and the Camden & Islington Foundation Trust in London will help us to recruit mentors. In both places, we will appoint a volunteer coordinator who will identify community groups, and train and supervise the mentors to support the older adults with intellectual disabilities. We have worked with older adults with intellectual disabilities, their carers, social care staff, and older people without disabilities in designing this study. They will continue to be involved if the research is funded. Everyone in the research team will play a part in sharing the findings with a variety of audiences. As we have done in the past, we will also prepare easy-read summaries.

What are the possible benefits and risks of participating?

The potential benefits are that the adults with a learning disability could extend their social networks and be more socailly included in their local communities. There are no perceived risks in participating in this study.

Where is the study run from? Ulster University (UK)

When is the study starting and how long is it expected to run for? February 2022 to April 2025

Who is funding the study?

National Institute for Health and Care Research (NIHR) Public Health Research Programme (PHR) 129125 (UK)

Who is the main contact?
Prof Laurence Taggart, l.taggart@ulster.ac.uk (UK)

# **Contact information**

# Type(s)

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# Additional identifiers

# Clinical Trials Information System (CTIS)

Nil known

# Integrated Research Application System (IRAS)

279668

# ClinicalTrials.gov (NCT)

Nil known

#### Protocol serial number

19/0066, IRAS 279668

# Study information

#### Scientific Title

A feasibility study of the clinical and cost-effectiveness of the MATILDA intervention to support older adults with intellectual disability to their improve health, wellbeing and social networks compared to usual care

#### Acronym

**MATILDA** 

#### **Study objectives**

Older adults with intellectual disability who access and engage in a local community group over a 6-month period will improve their health, wellbeing, and social networks

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Approved 14/06/2022, Office for Research Ethics Committees Northern Ireland (ORECNI) (Customer Care & Performance Directorate, Unit 4, Lissue Industrial Estate West, Rathdown Walk, Moira Road, Lisburn, BT28 2RF, UK; +44 (0)28 95361400; recb@hscni.net), ref: ORECNI 22 /NI/0067

#### Study design

Phase II 2-arm single-blind randomized feasibility study with 1:1 allocation study

# Primary study design

Interventional

#### Study type(s)

Quality of life

#### Health condition(s) or problem(s) studied

Older adults with intellectual disability

#### **Interventions**

Following informed consent, older adults with an intellectual disability will be randomised using a 1:1 ratio to the intervention group (Matilda) or control group, stratified by site. The randomisation will be generated by a member of staff based at the Northern Ireland Clinical Trials Unit not connected to the study. The research assistants at Ulster University and UCL will inform the adults with an intellectual disability which arm they have been allocated to. At the time of randomisation, each participant will be allocated a unique Participant Study Number, which will be used throughout the study for participant identification.

The Matilda intervention uses active mentoring to support older adults with an intellectual disability (aged 45 years or more) to engage in mainstream local community groups. Using 2 or 3 retired adults without an intellectual disability from local community groups to act as volunteers

or 'mentors', they then will support 1-2 older persons with an intellectual disability to join the group. The person with the intellectual disability will attend the group 1 to 3 times a week for six months. The focus of the Matilda intervention is to help older adults with an intellectual disability develop new social networks and friendships, with peers without an intellectual disability.

#### Process evaluation

The process evaluation intervention interviews will examine four key aspects of the feasibility of conducting a definitive trial of the Matilda intervention:

- 1. Intervention recruitment, adherence and reach
- 2. Intervention implementation
- 3. Intervention mechanisms, including receipt and acceptability and
- 4. The feasibility of implementing Matilda within a definitive randomised trial. These interviews will be undertaken with a sample of the older adults with an intellectual disability, mentors, and carers across both sites as part of the process evaluation that will take place post-intervention (1-2 months after the participants finished the intervention). These will be conducted by the RAs, digitally recorded and last approximately 40-60 mins.

#### Intervention fidelity and adherence

A checklist will be further developed to explore the fidelity of the Matilda intervention in greater detail in the process evaluation. In assessing the external validity, the extent of true collaboration in each local community group initiative will be assessed with the adults with an intellectual disability, carers, and mentors. To determine whether the Matilda intervention will be delivered as intended (adherence), each mentor will be asked to complete their own weekly paper checklist which details attendance, frequency, activities, adverse events, etc.

#### Intervention Type

Behavioural

#### Primary outcome(s)

Feasibility is assessed using the following outcome variables:

- 1. Recruitment measured using data collected in the case report form (CRF) at baseline
- 2. Consent measured using data collected in the CRF at baseline
- 3. Matching measured using data collected in the CRF after randomisation has taken place and during the process-evaluation interviews
- 4. Retention measured using data collected in the CRF at the end of the intervention at 6-months

#### Key secondary outcome(s))

Secondary feasibility is assessed using the following outcome variables:

- 1. Eligibility measured using data collected in the CRF at baseline
- 2. Recruitment rates and pathways measured using data collected in the CRF at baseline
- 3. Consenting rate measured using data collected in the CRF at baseline
- 4. Randomisation process measured using data collected in the CRF at baseline
- 5. Matching of mentors (and local community groups) and older adults with an intellectual disability measured using data collected in the CRF after randomisation has taken place, and during the process-evaluation interviews
- 6. Training and supervision measured using the process-evaluation interviews
- 7. Attendance levels measured using data collected in the CRF at 6-months post-randomisation
- 8. Drop-out rates measured using data collected in the CRF at 6-months post-randomisation
- 9. Retention of participants measured using data collected in the CRF at 6-months postrandomisation

#### Completion date

30/04/2025

# **Eligibility**

#### Key inclusion criteria

- 1. Mild/moderate intellectual disability
- 2. Living in the community with a family member(s) or in any type of community accommodation (residential/supported/shared lives)
- 3. 45 years old and over
- 4. Able to communicate verbally
- 5. Able to provide informed consent

#### Healthy volunteers allowed

No

#### Age group

Mixed

#### Sex

All

#### Key exclusion criteria

- 1. Severe/profound intellectual disability
- 2. Severe challenging behaviour
- 3. Unable to communicate verbally or in English Unable to provide consent
- 4. Already accessing mainstream community groups.

#### Date of first enrolment

01/02/2023

#### Date of final enrolment

31/05/2023

# Locations

#### Countries of recruitment

**United Kingdom** 

England

Northern Ireland

# Study participating centre Northern Health and Social Care Trust

Trust Headquarters Bretten Hall Bush Road Antrim United Kingdom BT41 2RL

Study participating centre Camden and Islington Mental Health (north Camden Site)

St. Pancras Hospital 4 St. Pancras Way London United Kingdom NW1 0PE

# Sponsor information

#### Organisation

**Ulster University** 

# Funder(s)

#### Funder type

Government

#### **Funder Name**

**NIHR PHR 129125** 

#### Alternative Name(s)

NIHR Public Health Research Programme, The Public Health Research (PHR), PHR

#### Funding Body Type

Government organisation

#### **Funding Body Subtype**

National government

#### Location

United Kingdom

# **Results and Publications**

Individual participant data (IPD) sharing plan

The data-sharing plans for the current study are unknown and will be made available at a later date

# IPD sharing plan summary

Data sharing statement to be made available at a later date

# **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Participant information sheet	version 2.0	16/05/2022	13/12/2022	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes