PROTOCOL ACRONYM:	Matilda	PROTOCOL NO:	19/0066

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PROTOCOL AUTHORISATION

Protocol Title	A feasibility study of the clinical and cost-effectiveness of the MATILDA intervention to support older adults with learning disability to their improve health, wellbeing and social networks compared to usual care
Protocol Short Title (if applicable)	Matilda Intervention
Protocol Number	19/0066
Protocol Version Number/Date	5.0 / 28.012.23
Protocol Amendments	

A review of the protocol has been completed and is understood and approved by the following:

Laurence Taggart		_____ / _____ / _____
Chief Investigator Name	Signature	Date DD/MM/YYY
Brendan Bunting		_____ / _____ / _____
Statistician	Signature	Date DD/MM/YYY

Table of Contents

LIST OF ABBREVIATIONS

Abbreviation / Acronym	Full Wording
AE	Adverse Event
AR	Adverse Reaction
CAN	Compass Advocacy Network
CI	Chief Investigator
CRF	Case Report Form
CTA	Clinical Trial Authorisations
EQ-5D-Y	EuroQol-5 Dimension-Youth
GCP	Good Clinical Practice
GP	General Practitioner
HRA	Health Research Authority
HRQoL	Health Related Quality of Life
HTA	Health Technology Assessment
LD	Learning Disability
IRAS	Integrated Research Application System
ISF	Investigator Site File
ISRCTN	International Standard Randomised Controlled Trial Number
NICE	National Institute for Health and Care Excellence
NICTU	Northern Ireland Clinical Trials Unit
NIHR	National Institute for Health and Care Research
PI	Principal Investigator
PIS	Participant Information Sheet
PPI	Personal Public Involvement
QALY	Quality Adjusted Life Year
R&D	Research & Development
RA	Research Associate
REC	Research Ethics Committee
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SAR	Serious Adverse Reaction
SDV	Source Data Verification
SUSAR	Suspected Unexpected Serious Adverse Reaction
TAU	Treatment As Usual
TMF	Trial Master File
TMG	Trial Management Group
TSC	Trial Steering Committee
UU	Ulster University
WHO	World Health Organisation

1 STUDY SUMMARY

Scientific title	**Full Title:** A feasibility study of the clinical and cost-effectiveness of the MATILDA intervention to support older adults with a learning disability to improve their health, wellbeing and social networks compared to usual care **Short Title:** Matilda Intervention for Adults with a Learning Disability
Public title	Improving the health, wellbeing, and social networks of older adults with a learning disability: The Matilda Study
Health condition(s) or problem(s) studied	Ageing in adults with learning disability.
Study Design	Phase 11 This is a 2-arm, single-blind, randomised feasibility study with 1:1 allocation in Northern Ireland and North London.
Study Aim and Objectives	**Aim** To undertake a randomised feasibility study of the Matilda intervention to improve health, wellbeing, and social networks by facilitating adults with a learning disability to engage in their local community group and to compare this with Treatment as Usual (TAU). **Objectives** 1. Assess eligibility, recruitment rates and pathways, consenting rate, randomisation process, ability to match mentors (and local community groups) and older adults with a learning disability, attendance levels, drop-out rates, and retention of participants 2. Explore the views of the stakeholders (adults with a learning disability, carers, and mentors) about the acceptability of the Matilda intervention 3. Determine the appropriateness and acceptability of the outcome measures to older adults with a learning disability, carers, and mentors 4. Measure the fidelity of mentors in supporting older adults with a learning disability 5. Estimate the effect of the Matilda intervention on the outcomes for older adults with a learning disability (health, wellbeing, and social connectedness), family carers (health, well-being) and mentors (wellbeing, attitudes to people with a learning disability) at 6 and 12-months post intervention 6. Provide preliminary information about treatment effects to inform the sample size for a full trial 7. Explore the potential cost-effectiveness of the Matilda intervention 8. Record any adverse events and unintended consequences of the Matilda intervention
Study Intervention	Matilda: Older adults with a learning disability to access and engage in a local community group over a 6-month period supported by trained mentors (without an learning disability) between 1 and 3 times per week
Primary Outcome	The primary outcome is feasibility (i.e., recruitment, consent, matching, retention, etc.).

Key Secondary Outcomes	**Other feasibility outcome measures:** Assess eligibility, recruitment rates and pathways, consenting rate, randomisation process, matching of mentors (and local community groups) and older adults with a learning disability, training and supervision, attendance levels, drop-out rates, and retention of participants.
Key Inclusion and Exclusion Criteria	**<u>Older person with a learning disability</u>** **Inclusion criteria:** • Mild / moderate learning disability • Living in the community with at least one family member or in any type of community accommodation (residential/supported/shared lives) • 45 years or older • Able to communicate verbally • Able to provide informed consent. **Exclusion criteria:** • Severe / profound learning disability • Severe challenging behaviour • Unable to communicate verbally or in English • Unable to provide consent • Already accessing mainstream community groups. With regards to severe challenging behaviour, the staff will be asked to complete the Aberrant Behaviour Checklist (Irritability subscale) (ABC-I) to assess for aggression because this is the biggest issue. The ABC-I has a median of 20 (Hassiotis et al 2019) so we will exclude those scoring above the median. **<u>Family carers</u>** **Inclusion criteria:** • Be a family carer of an older person with a learning disability • Provide written consent **Exclusion criteria:** • Paid carer • Consent declined **<u>Mentors</u>** **Inclusion criteria:** • Attend a local community group • Provide written consent • Complete registration (incl. obtaining 2 references) and declaration of convictions forms **Exclusion criteria:** • Have a criminal record • Consent declined
Countries of Recruitment	Northern Ireland and England
Study Setting	Health and Social Care Settings in the Community
Target Sample Size	64
Study Duration	30 Months

2 STUDY TEAM

Chief Investigator	**Professor Laurence Taggart** Ulster University
Co-Investigators	**Professor Angela Hassiotis** University College London

	Professor Assumpta Ryan Ulster University
	Professor Roger Stancliffe Sydney University
	Professor Mike Clarke Northern Ireland Clinical Trials Unit / Queen's University Belfast (QUB)
	Mrs Lindsay Armstrong Volunteer Now
	Mrs Janet Schofield COMPASS Charity
Statistician	**Professor Brendan Bunting** Ulster University
Health Economist	**Professor Carian O'Neill** QUB
Primary Sponsor	Ulster University, Mr Nick Curry, Head of Research Governance, Room BD-04-005, Ulster University, Belfast Newtownabbey, Co Antrim, BT15 1ED
Primary Sponsor's Reference	19/0066
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3 ROLES AND RESPONSIBILITIES

3.1 Funder

The National Institute for Health and Care Research (NIHR) PHR Programme will be providing the research costs to the Matilda Project (NIHR129125).

The funder has no role in the study design, data acquisition, analysis, interpretation, or manuscript preparation.

3.2 Sponsor

The Ulster University (UU) will act as Sponsor for the study and the Chief Investigator (CI) will take overall responsibility for the conduct of the trial. Ulster University will put individual site agreements in place.

3.3 Trial Oversight Committees

The CI will have overall responsibility for the conduct of the study including preparing approval and governance applications (REC and research governance), safety reporting, site initiation/training, monitoring, statistical analysis, and reporting. The health economic analysis will be undertaken by QUB.

The CI and Research Associate (RA) at UU will be responsible on a day-to-day basis for overseeing and co-ordinating the work of the multi-disciplinary trial team. Additional trial specific oversight committees will include a Trial Management Group (TMG), Trial Steering Committee (TSC) and Data Management & Ethics Committee (DMEC). The NICTU will facilitate the randomisation of participants.

3.4 Trial Management Group (TMG)

A TMG will be established and chaired by the CI. It will have representatives from the co-investigators and will meet face to face or by teleconference bi-monthly and will communicate between times via telephone, online tools (e.g., Teams) and email as needed. The roles and responsibilities of the TMG will be detailed in the TMG Charter. Meetings will be formally minuted and a list of actions recorded and stored in the Trial Master File (TMF). All day-to-day activity will be managed by the RA at UU.

3.5 **Trial Steering Committee (TSC)**

The TSC will provide oversight with respect to the conduct of the study on behalf of the Funder and Sponsor. A group of experienced clinicians and trialists will act as a TSC with an independent Chair and at least 75% independent membership. Janet Schofield (Director of CAN in Northern Ireland) will sit on the TSC and will be the PPI Representative. Membership and roles of the TSC will be listed in the TSC Charter.

The TSC will meet up to twice per year and be in regular contact via phone, online tools, and email. Observers may be invited to attend the TSC meetings, such as the Sponsor or Funder representatives. Meetings will be formally minuted and stored in the TMF.

The TSC will be responsible for monitoring and supervising the progress of the study and will advise on the trial protocol, assess the pilot against the progression criteria, and provide recommendations to the Sponsor and Funder.

3.6 **Data Monitoring and Ethics Committee (DMEC)**

An independent DMEC will be convened and will comprise of at least 2 independent clinicians with relevant experience in clinical trials, and an independent statistician. One of the independent clinicians will have experience in the regulatory aspects of clinical trials. It will have an independent Chair and will meet at least twice a year and additional meetings can be convened if necessary. Janet Schofield (Director of CAN in Northern Ireland) will sit on the DMEC and will be the PPI Representative. Meetings will be formally minuted and the DMEC chair will approve any minutes prior to circulation to the rest of the members. The DMEC chair will also provide DMEC recommendations to the TSC who will decide what actions, if any, are required. Copies of all documentation will be stored in the TMF.

The role of the independent DMEC will be detailed in the DMEC charter but will include, monitoring the data and making recommendations to the TSC on whether there are any ethical reasons why the trial should not continue. The DMEC will consider the need for any interim analysis; advising the TSC regarding the release of data and/or information; and will consider data emerging from other related studies.

3.7 **User Involvement or any other relevant committees**

The specific needs of individuals with a learning disability will be taken into consideration when preparing information leaflets and consent forms. Janet Schofield will represent the individual's perspective on the TSC ensuring that the trial remains considerate of the needs of persons living with a learning disability and their families.

4 BACKGROUND AND RATIONALE

4.1 Background Information

People with a learning or an intellectual disability are living significantly longer than in past decades, but they are experiencing the ageing process earlier and at a faster rate than people without a learning disability (1, 2). This new ageing population is predicted to grow four times faster than the overall adult a learning disability population, putting pressure on an already stretched NHS (3). This is a new ageing population whose needs have been underspecified and under-researched.

In comparison to non-learning-disabled older adults where chronological age (normally 60-65 years), significant life events such as leaving a job or career and receiving a pension (indicating 'retirement') do not occur for older adults with a learning disability (5; 6). Most adults with a learning disability are not in paid employment, there is no identified and agreed age for a person to 'retire' (since there may be nothing for them to retire from), and older adults with a learning disability do not get a work-related pension. It is therefore purported that the concepts of 'retirement' and 'transition' from adult to mainstream ageing services are alien to many adults with a learning disability, their family carers and to many statutory and voluntary disability service providers. Therefore, many older adults with a learning disability have few if any opportunities to be included in their local communities and to engage with older adults without a learning disability (7). Being cut-off from their local community leads to feelings of isolation, loneliness, and depression. Both learning disability and mainstream older people's services have not, to date, considered how adults with a learning disability are included in their local communities and the potential benefits of this.

There is now a greater recognition and emphasis on providing more inclusive policies and activities to connect older adults with a learning disability to their local communities and with their peers without disabilities (7; 8; 9). We will use this study to build on the mandate that this new ageing learning disability population should be supported to develop and maintain inclusive relationships within their local communities, as highlighted in the NICE 2018 guidelines (ng96) for supporting older adults with a learning disability (10).

4.2 Rationale for the Study

'Loneliness' and 'social isolation' have been extensively examined in the general population and ageing fields and found to correlate strongly with negative outcomes, including physical health problems, depression, and poorer quality of life (11; 12). The higher rates of physical and mental health problems are leading to significant costs for the NHS.

Furthermore, as people with a learning disability age, they are more likely to have a greater risk of increased social isolation, loneliness / depression and poorer quality of life compared to their non-disabled peers (13; 14). This is despite older adults with a learning disability wanting to remain active and be socially connected to their local communities (15) and the acknowledgement that people with a learning disability can also experience 'loneliness' as result of social isolation. For example, Petroutsou et al. (2018) (16) undertook a systematic review of loneliness in people with a learning disability, highlighting loneliness was a more common experience in this population (50.4%) compared to the general population (10.6%). Cognitive difficulties, communication limitations, underdeveloped social skills, and limited friendships, social networks and opportunities were frequently cited as reasons for such disparities (16; 17). While the negative attitudes of the general population to people with a learning disability contributed to their increased susceptibility towards loneliness (17).

NICE guidelines (ng96) (10) recommended that commissioners and service providers should ensure that older people with a learning disability have 'equal access to a range of mainstream older people's services, linking into voluntary sector umbrella groups, providing opportunities to meet up and socialise through social clubs and support groups (dancing, swimming, bowls, using the gym, organised walks)' but how to do this effectively is not clear. This study offers a unique opportunity to build **'socially connected age friendly communities'** (18; 19) for older adults with a learning disability to develop and maintain social connections; thereby increasing their social networks and friendships, which will then impact upon their wellbeing and quality of life. This would be in keeping with a meta-analysis found that improving social skills, enhancing social support, and providing opportunities for social engagement in the older general population could effectively diminish the impact of loneliness (20).

One approach to achieving this has been the use of befriending schemes. These schemes are characterised by a one-to-one relationship, where a volunteer supports a person to engage in local community activities. This support is usually prescriptive in terms of time and duration. Befriending schemes target individuals who are lonely, isolated and have limited opportunities for social and community participation, by enhancing social networks and community participation. The causal mechanisms of befriending on health outcomes are uncertain, but social support is thought to be the core factor because it can increase the person's perceived level of support, resulting in improved psychological wellbeing. A systematic review found that befriending reduced depression for those with mental or physical health problems when compared to treatment as usual: but it did not focus on people with a learning disability (21). Befriending schemes can also benefit the volunteers who gain greater awareness and empathy for a particular population (22). Wu (2011) (23) highlighted wider societal and economic benefits of such befriending schemes such as reduced burden on government spending, strengthening of social connections between different sectors and organisations within the community, and more cohesive communities.

Florides (24) undertook a feasibility study of a one-to-one befriending scheme for 15 adults with a learning disability (aged ≥18 years), and results were promising: 53% reported a decrease in isolation and the confidence of 40% increased. There is currently one ongoing NIHR-funded feasibility randomised study examining one-to-one befriending by volunteers compared to usual care, targeting depression in adults with a learning disability in England (25). The befriending scheme in that study focuses on providing friendship to an adult with a learning disability and supporting the person to access a range of activities in the community (going for a coffee, cinema, etc) and/or spending time at home. The volunteer (befriender) and person with a learning disability are expected to meet once a week for one-hour, for six months. However, these studies do not target older adults with a learning disability and the outcomes examined differ significantly from those that will be measured in this project.

4.3 **Rationale for the Intervention**

A team of Australian researchers undertook a feasibility study of the Transition to Retirement (TTR) project, using active mentoring, to support 29 older adults with a learning disability (aged ≥45 years) to engage in mainstream local community groups with a matched comparison group (26). Using two or three retired adults without a learning disability from local community groups to act as volunteers or 'mentors', they supported one older person with a learning disability to join the group. The person with the learning disability attended 1 to 3 times a week for six months. The focus of the TTR project was to help older adults with a learning disability who were in supported employment to develop new social networks and friendships, with peers without a learning disability. The older adults with a learning disability reported increased social connectedness, less loneliness, improved wellbeing, and better quality of life after engaging in the TTR project. One surprising result was that many of the older adults with a learning disability continued to attend the local community group with their mentors and other members of the group after the study had ended.

In preparation for this study, we carried out seven focus groups to identify the needs of older adults with a learning disability, potential mentors, family carers and managers, and how to enable older adults with a learning disability to participate in local community groups. This allowed us to adapt the TTR social intervention for a UK context to support this population to access local community groups. We changed the name of the intervention to Matilda (Managing Activities Together, to Involve older people with a learning disability in their local community). It aims to provide local community groups and mentors with the opportunity to become more integrated with older adults with a learning disability. The adapted intervention aims to reduce social isolation, depression and improve quality of life for the older adults with a learning disability. The mentors may also indirectly improve their health and wellbeing.

The study builds on the adaptation of the TTR project for a UK context. It will use two or three mentors to support one older person with a learning disability compared to one befriender / volunteer. Some of the restrictions of the befriender role is its limited duration, leading to the person with a learning disability feeling distressed after the intervention ends, excessive responsibility placed on a single befriender / volunteer and a lack of sustainability into the wider community (27; 28). Whereas the use of two or three mentors supporting one older person with a learning disability in a local community group can lessen the responsibility on the volunteers, offer greater opportunities for the person with a learning disability to develop their networks in the group and within their wider community. This should develop naturally occurring friendships that can be sustained for the longer term.

We are now in a position to undertake a feasibility study of the Matilda intervention to promote health, wellbeing, and social connectedness as a prelude to a definitive trial. If this feasibility study is favourable and a subsequent definitive trial is successful, the Matilda project may be an attractive option for commissioners of social care services. It would offer a low-cost sustainable intervention that uses existing local community social infra-structures instead of costly disability services that would be restricted to adults with a learning disability.

4.4 **Rationale for Comparator**

Older adults with a learning disability who are randomly allocated to the control group will receive usual care (treatment as usual: TAU) and three social group events (outings) and will not be offered any access to an older person's mainstream community group. We will monitor TAU for this population across the two countries.

5 STUDY AIM AND OBJECTIVES

5.1 **Research Hypothesis**

The Matilda intervention will be feasible and acceptable, and this study will lead to a full-scale randomised trial being implemented.

5.2 **Study Aim**

The study will determine the feasibility and acceptability of a full-scale randomised trial of the Matilda intervention to improve health, wellbeing, and social networks by facilitating older adults with a learning disability to engage in their local community compared with TAU.

5.3 **Study Objectives**

5.3.1 Primary objective

To conduct a UK based, multicentre, randomised feasibility trial to determine the feasibility and acceptability of the Matilda intervention for adults with a learning disability targeting health, wellbeing and social networks compared to TAU.

5.3.2 Secondary objectives

1. Assess eligibility, recruitment rates and pathways, consenting rate, randomisation process, ability to match mentors (and local community groups) and older adults with a learning disability, attendance levels, drop-out rates, and retention of participants
2. Explore the views of the stakeholders (adults with a learning disability, carers and mentors) about the acceptability of the Matilda intervention
3. Determine the appropriateness and acceptability of the outcome measures to older adults with a learning disability, carers, and mentors
4. Measure the fidelity of mentors in supporting older adults with a learning disability

5. Estimate the effect of the Matilda intervention on the outcomes for the older adults with a learning disability (health, wellbeing, and social connectedness), family carers (health, well-being) and for the mentors (wellbeing, attitudes to people with a learning disability) at 6 and 12-months post intervention
6. Provide preliminary information about treatment effects to inform the sample size for a full trial
7. Explore the potential cost-effectiveness of the Matilda intervention
8. Record any adverse events and unintended consequences of the Matilda intervention

6 STUDY DESIGN

6.1 Study Design

This is a 2-arm, single-blind, randomised feasibility study with 1:1 allocation, which will be conducted in Northern Ireland and London. 64 older adults with a learning disability will be randomly allocated to either the Matilda intervention plus usual care or usual care with three group recreational activities with other older adults with a learning disability (active control arm). The intervention will last six months. The primary outcome is feasibility (i.e., recruitment, consent, matching , retention, etc.). Outcome measures will be collated at baseline, 6 and 12-months post intervention. We will conduct a process evaluation and a health economic evaluation.

PICOST framework

Population: Adults with a mild / moderate learning disability, ≥45 years of age
Intervention: Matilda: Older adults with a learning disability to access and engage in a local community group over a 6-month period supported by trained mentors (without a learning disability) between 1 and 3 times per week
Comparator: Usual care, receipt of local disability services day-care and/or day opportunities, along with three peer recreational activities
Outcomes: Feasibility outcomes and health and well-being measures at baseline, and 6- and 12-months post intervention.
Setting: Local community setting
Timing: The intervention will last six months.

6.2 Feasibility Randomised Controlled Trial Study

The feasibility trial will run for 30 months to assess recruitment rates and retention for the measuring of the primary outcome at 6 months. This will also allow us to identify any key difficulties and address them in preparation for a potential definitive randomised trial. The two clinical sites will recruit a total of 64 older adults with a learning disability during this period.

6.3 Progression criteria

We will apply predetermined progression criteria as set by Avery et al. (43). This will be based on the feasibility outcome data pertaining to recruitment, matching older adults with a learning disability to mentors, retention rates and reasons for attrition, programme attendance, protocol adherence and the completion of outcome measures. A traffic light system will be used to inform whether the study should progress to a full trial, whether revisions are required or whether it should be stopped:

GREEN:
1) Recruitment rates of at least 70% of adults with a learning disability and mentors who are approached consenting to randomisation across both sites.

2) Acceptability of and engagement in the Matilda intervention of at least 60% of the adults with a learning disability allocated to this arm across both sites.

3) Acceptability of the matching process, and engagement in the Matilda intervention of at least two mentors for at least 60% allocated to this arm across both sites.

4) Acceptability of the appropriateness of the outcome measures for at least 60% of the adults with a learning disability and their mentors across both sites.

5) Retention of at least 60% of the recruited adults with a learning disability and their mentors at the 6- and 12-months follow-up across both sites.

A trial would not be appropriate if there was no signal of efficacy but if there is and if these progression criteria are met, then it would be appropriate to move on to a definitive trial.

AMBER: Revision in procedures will be instigated if:

1) Recruitment falls between 69-40% or there are difficulties in intervention delivery (acceptability or engagement in the Matilda intervention of 40-60% of the older adults with a learning disability or engagement of at least two of the mentors for 40-60% allocated to this arm) or

2) Retention (acceptability of the appropriateness of the outcome measures for 40-60% of the adults with a learning disability and their mentors or

3) Retention of 40-60% of the recruited older adults with a learning disability and their mentors at the 6 and 12-months follow-up) across both sites.

RED: We will not move on to a definitive trial if:

1) Either mentors or adults with a learning disability (<39%), or

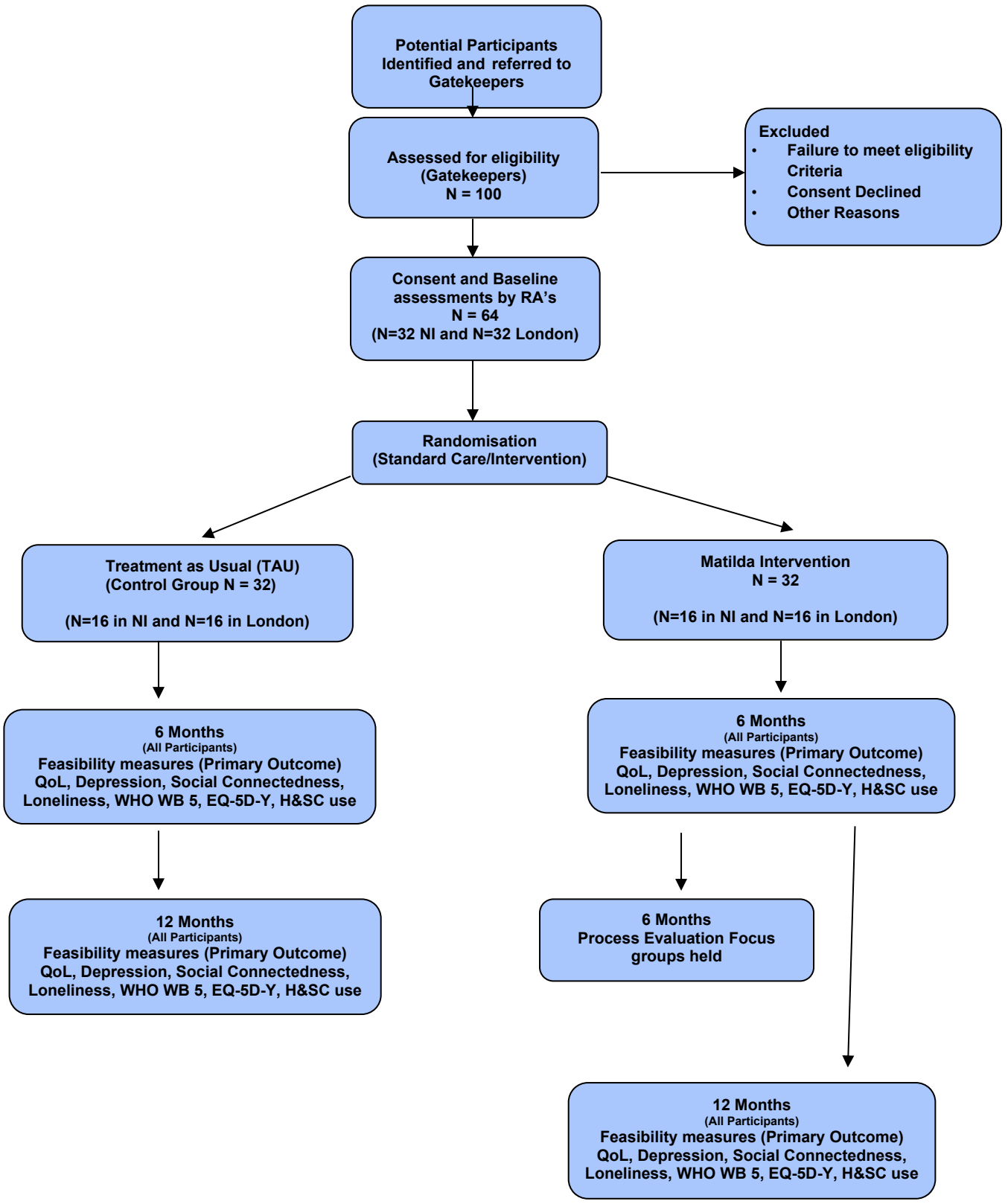
2) The intervention is not acceptable to at least 40% of older adults with a learning disability or mentors, or

3) We cannot retain at least 40% of participants at the 6- and 12-months follow-up across both sites.

We will monitor recruitment rates in each site, and this will be reviewed by both site's PIs and RAs in weekly telephone or online meetings, identifying reasons for any recruitment problems in real time. We will have a wide recruitment network from the outset

including user friendly information in how to promote the study and meetings with various local community organisations. We will identify champions in both sites to help study promotion.

6.3 Study Schematic Diagram



6.4 Study timeline and key tasks

The total duration of the study will be 30 months, including follow up at 6 and 12 months after randomisation for all participants. Details of specific trial tasks and timelines are presented in Table 2. We will open the two trial sites within 1- 6 months. The feasibility study will run between months 5-27.

The total recruitment period will last for 13 months, with a follow up period of 12 months for all participants. There will be 4 months at the end for final data analysis, reporting and close.

Table 2. Study timeline Gantt chart

Phase	PHASE 1									PHASE 2									PHASE 3																	
Milestones	Ethics and Research Governance (non-funded)			Set up and recruitment of participants				Baseline data collection and randomisation		Matching process , train the trainers and planning meetings						Main study			6 month data collection, and process evaluation and data analysis								12 month data collection, data analysis and health economic evaluation				Final data analysis. Write Report and papers. Close down		
Project Month	-6	-3	-1	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30
Calendar Month	Sep-21	Nov-22	Jan-23	Feb-23	Mar-23	Apr-23	May-23	Jun-23	Jul-23	Aug-23	Sep-23	Oct-23	Nov-23	Dec-23	Jan-24	Feb-24	Mar-24	Apr-24	May-24	Jun-24	Jul-24	Aug-24	Sep-24	Oct-24	Nov-24	Dec-24	Jan-25	Feb-25	Mar-25	Apr-25	May-25	Jun-25	Jul-25
Milestone 1: Apply and obtain ethical approval and research governance in N Ireland and London	X	X	X																														
Milestone 2: Recruitment of research staff and Volunteer Co-ordinators in N Ireland and London		X	X																														
Milestone 3: Set up: TSC and DMEC meeting						TSC		DMEC								TSC				DMEC							TSC				DMEC	TSC	
Milestone 4: Identification and recruitment of local community groups and mentors				X	X	X	X	X	X	X	X	X	X	X	X	X	X																
Milestone 5: Identification and recruitment of 64 adults with learning disability in N Ireland and London				X	X	X	X	X	X	X	X	X	X	X	X	X																	
Milestone 6: Baseline assessments of adults with learning disability and family carers						X	X	X	X	X	X	X	X	X	X	X																	
Milestone 7: Baseline assessments of mentors										X	X	X	X	X	X	X																	
Milestone 8: Train the mentors										X	X	X	X	X	X	X	X																
Milestone 9: Randomisation takes place							X	X	X	X	X	X	X	X	X	X																	
Milestone 10: Matching process of adults with learning disability, mentors and groups											X	X	X	X	X	X	X																
Milestone 11: I Intervention group planning meetings: 16 to he held in N Ireland over 16 weeks											X	X	X	X	X	X	X																
Milestone 12: Intervention group planning meetings: 16 to he held in London over 16 weeks											X	X	X	X	X	X	X																
Milestone 13: Six-month Interventions can start in these months in N Ireland											X	X	X	X	X	X	X	X	X	X	X	X	X										
Milestone 14: Six-month Interventions can start in these months in London											X	X	X	X	X	X	X	X	X	X	X	X	X										
Milestone 15: Fidelity checks in N Ireland and London												X	X	X	X	X	X	X	X	X	X	X	X										
Milestone 16: Comparator group to meet every second month													X		X		X		X		X												
Milestone 17: Data collection at 6-month post intervention follow-up of adults with learning disability and family carers																	X	X	X	X	X	X	X										
Milestone 18: Data collection at 6-month post intervention follow-up of mentors																	X	X	X	X	X	X	X										
Milestone 19: Process evaluations with adults with learning disability, family carers, mentors and others in N																	X	X	X	X	X	X	X										
Milestone 20: Analyse process evaluation data																				X	X	X	X	X	X								
Milestone 21: Data collection at 12-month post intervention follow-up of adults with learning disability and family carers including health economic data collection																							X	X	X	X	X	X	X				
Milestone 22: Data collection at 12-month post intervention follow-up of mentors including health economic data collection																							X	X	X	X	X	X	X				
Milestone 25: Close down: Analysis of all data; writing final report and papers for publication																												X	X	X	X	X	X
Milestone 26: Dissemination of results; preparing NIHR definitive trial application																															X	X	X
Milestone 27: TSC meeting: Close study																																	X

6.5 **End of Study**

The end of trial will be when database lock occurs for the final study analysis after 64 participants have been randomised and followed up.

The study will be stopped early if:

- Mandated by the Research Ethics Committee,
- Mandated by the Sponsor e.g., following recommendation from the TSC/DMEC.
- Funding ceases.

The REC that originally gave a favorable opinion of the trial will be notified in writing if the trial has been concluded or stopped early.

7 Participants

7.1 Study Setting

The study will take place in Health and Social Care settings in the community in one region of Northern Ireland (Northern Health and Social Care Trust: NHSCT) and in one region of London. We have chosen a range of clinical sites across the NHSCT and London (Camden and Islington) to maximize recruitment across a large population and improve the applicability of our results.

The clinical sites cover a range of urban and semi-rural areas and include areas with high levels of deprivation and London's population is ethnically and culturally diverse. We will use a range of mainstream community older persons groups to deliver the Matilda intervention.

To be involved in the study, the older person mainstream community groups and mentors at the clinical sites must be prepared to participate in the Matilda training package and be prepared to support the older person with a learning disability to the group. They must also demonstrate and document a willingness to comply with the protocol and regulatory requirements.

A list of study sites will be maintained in the TMF.

7.2 Study Population

- Older adults with a learning disability (≥45 years) living in the community.

7.3 Eligibility Criteria

Participants will be assessed using the inclusion and exclusion criteria as set out below. Eligibility to participate in the trial will be confirmed by a person who is named and delegated the role on the site Delegation Log.

7.4 Inclusion criteria

Participants will be eligible to participate in the study in accordance with the following criteria:

Older person with a learning disability

Inclusion criteria:
- Mild / moderate learning disability
- Living in the community with a family member(s) or in any type of community accommodation (residential / supported / shared lives)
- ≥45 years
- Able to communicate verbally
- Able to provide informed consent

Several definitions of learning disability are used in the UK. A commonly used one is from Valuing People: A new strategy for learning disability for the 21st century, the government White Paper for England about health and social care support for people with a learning disability (23). It explains that a learning disability includes the presence of a significantly reduced ability to understand new or complex information or to learn new skills; a reduced ability to cope independently; an impairment that started before adulthood, with a lasting effect on development. To explain the wide range of different abilities, the idea of a continuum of learning disability has been used for some time:

Mild learning disability – A person who is said to have a mild learning disability is usually able to hold a conversation and communicate most of their needs and wishes. They may need some support to understand abstract or complex ideas. People are often independent in caring for themselves and doing many everyday tasks. They usually have some basic reading and writing skills. People with a mild learning disability quite often go undiagnosed.

Moderate learning disability – People with a moderate learning disability are likely to have some language skills that mean they can communicate about their day-to-day needs and wishes. They may need some support with caring for themselves, but many will be able to carry out day to day tasks with support.

Family / paid carers

Inclusion criteria:
- Be a family or a paid carer of an older person with a learning disability
- Provide written consent

Mentors

Inclusion criteria:
- Attend a local community group.
- Provide written consent.
- Complete registration (including obtaining 2 references) and declaration of convictions forms.

7.5 Exclusion criteria

Older person with a learning disability

Exclusion criteria:
- Severe / profound learning disability.

- Severe challenging behaviour.
- Unable to communicate verbally or in English.
- Unable to provide consent.
- Already accessing mainstream community groups.

With regards to severe challenging behaviour, the staff will be asked to complete the Aberrant Behaviour Checklist (Irritability subscale) (ABC-I) to assess for aggression as this is the biggest issue. The ABC-I has a median of 20 (Hassiotis et al. 2019) so we will exclude those scoring above the median.

Family / paid carers

Exclusion criteria:
- Paid Carer
- Consent declined

Mentors

Exclusion criteria:
- Have a criminal record
- Consent declined

8 Interventions

8.1 Study Intervention and Comparator

The original TTR social intervention was established to explore the retirement options for older adults with a learning disability engaged in employment in Australia, and to assess possible pathways to retirement (26). The theoretical underpinnings of the TTR intervention are the Active Support Model (30) and the Co-Worker Training Model, where potential mentors are provided with training and then matched with an older adult with a learning disability to access a local community group: it is a peer led intervention.

The TTR intervention has three components: 1) promoting the concept of retirement, 2) laying the groundwork for inclusion of would□be retirees with a learning disability, and 3) constructing the reality. The third component comprises five stages: planning, locating a group, mapping new routine, recruiting, and training mentors, and monitoring and ongoing support (31). Adults with a learning disability reported increased social connectedness, less loneliness, improved wellbeing, and better quality of life after engaging in the TTR project. No data were collected on the benefits of the project for the mentors. In consultation, it was agreed that this intervention could be adapted to older people with a learning disability generally, regardless of employment status.

With funding from the Northern Ireland Research & Development Office, we adapted the TTR project to an UK context. We held 7 focus groups with senior staff from local disability and mainstream older person charities, potential mentors, older adults with a learning disability and their carers. The challenges and supports to help adults with a learning disability participate in local community groups were explored. There was a willingness by all involved to participate in a social connectedness project, but it was noted that mechanisms would need to be put in place, which included training and ongoing support for mentors. Carers had concerns which included losing day-care places; transport issues; cost; and negative attitudes and perceptions of what to expect. The adults with a learning disability saw it as an opportunity to ‘learn something new’ and ‘make new friends’. The idea of going to a local community group and being supported by a small group of mentors was welcomed.

Three co-production workshops with key stakeholders explored how the TTR project could be adapted for a UK context. The key issues identified were agreement to give less emphasis to retirement, reflected in its new acronym ‘Matilda'; a pledge from the NHSCT to provide staff to support the Volunteer Co-ordinator to identify and support adults with a learning disability in accessing local community groups; confirmation from the NHSCT that study participants would not lose any existing support provided by learning disability services; need for early identification of local community groups and personal initial communication; increased focus on ongoing monitoring and support between adults with a learning disability / mentors / Volunteer Co-ordinator and carers, and the priority to safeguard vulnerable adults.

Matching of adults with learning disabilities, mentors, and local community groups
The Volunteer Co-Ordinator and the disability staff in each site will meet with one older adult with a learning disability and their carers at a time, to explore the person’s needs, capabilities, interests, and hobbies, to identify a suitable local community group and discuss the logistics of attendance (availability of both the adult with the disability and the mentors, transportation to and from the community group, when and where the older adults and mentors would meet etc).

The Volunteer Co-ordinator will support the two or three mentors to facilitate the person with the learning disability to attend the community group. This will continue until the mentors feel they are confident in supporting the adult with the learning disability, and the adult is comfortable with the arrangements. Based upon previous experience we anticipate this will take approximately 6 to 12 weeks. Support will be individually tailored, with the Volunteer Co-ordinator regularly following up to ensure that the adult with the learning disability is attending and actively involved in the community group (visits, phone, text). Mentors and carers will be able to contact the Volunteer Co-ordinator and learning disability staff for advice. By their nature, local community groups such as men's sheds, sporting activities, knitting, or gardening groups vary in their frequency and duration, typically between 1 to 4 hours over 1 to 3 sessions per week. The adult with the learning disability will be supported by their mentors to attend the group and facilitate their involvement with the group for 6 months.

We accept that there is the potential that a local community group and mentors may not be found for some people with a learning disability. The Volunteer Co-ordinator and disability staff in each site will hold a series of meetings to try to match the appropriate person to their desired activity and suitable mentors. If a person with the learning disability cannot be matched to a community group, they might need to be withdrawn from the study and, if so, this will be clearly recorded and reported. That

said, experience from the project in Australia (Stancliffe et al. 2015) reported that over 90% of participants with a learning disability found a satisfactory match.

Given that we will be recruiting and consenting adults with learning disabilities over a six-month intervention arm, then the matching will take place after consenting the adults with learning disabilities. It will be during the matching process when we will recruit and consent the mentors during the months Nov 23 – March 24.

Based upon some of the challenges we have encountered in the matching process, we now have two different approaches to matching a person with a LD to a community group:

1. For some potential mentors in some of the community groups they will receive some initial training before matching takes place. This will be mainly for those larger groups where there are paid staff.

2. For other community groups, the person with LD will be supported into the community group by the volunteer co-ordinator for a few weeks until a mentor(s) can be identified and then training offered. This will be mainly for those smaller groups where there are no paid staff.

3. Each community group will be assessed individually for how best to approach them and the mentors.

Comparator Group
Participants randomised to the Matilda group will also receive TAU, ensuring that they do not lose any treatments or care that are standard. Those in the control group will receive TAU and will be offered three group recreational activities. TAU will be established at the start of the study and again at the end of the study. The participants in control group will complete data gathering instruments at baseline, 6 and 12 months.

8.2 **Assignment of interventions**

8.2.1 Sequence Generation

The randomisation sequence will be saved in a restricted section of the TMF which will only be accessible to the statisticians and not to individuals who enrol or assign interventions. It will be generated using random permuted blocks of mixed size in nQuery.

8.2.2 Allocation Concealment Mechanism

The randomisation sequence will be concealed by using a centralised randomisation system and a participant's allocation will not be revealed until they have consented to join the trial.

8.2.3 Randomisation Procedure

Following informed consent, older adults with a learning disability will be randomised using 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 RAs at Ulster University and UCL will inform the adults with a learning 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.

8.2.4 Blinding

The RAs conducting the assessments will not be blinded to each participant's allocated group. It is not possible to blind the adults with a learning disability and the mentors to arm allocation.

8.3 **Outcome Measures**
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8.3.1 Primary Outcome Measure

To examine the feasibility outcomes of the Matilda intervention (i.e., assess eligibility, recruitment rates and pathways, consenting rate, randomisation process, matching of mentors (and local community groups) and older adults with a learning disability, training and supervision, attendance levels, drop-out rates, and retention of participants).

8.3.2 Secondary Outcome Measures

Outcome measures for adults with learning disabilities: These have been chosen based on the measures used in the original TTR project and our experience with older adults with a learning disability. They reflect the total measurement load that adults with a learning disability have been willing to bear, and the need for brevity and good psychometric properties.

Health related QOL: WHOQOL-Dis is a measure of health-related quality of life developed by the WHO (33). This 26-item short version consists of two benchmark items on general health (not used in the scoring) (one general QOL item, one general health item) and 24 specific items which generate a total score and four domains: physical health, psychological health, social relationships, and environment QOL. Each item is answered on a 5-point Likert scale, which assesses the intensity, capacity, frequency, and evaluation of QOL facets with respect to the last two weeks. The WHOQOL has been validated in non-disabled individuals.

Depression: Glasgow Depression Scale for adults with a learning disability (34), which is a 20-item self-report scale. It has been used in several psycho-interventions for adults with a learning disability and found to have good psychometric properties. Scores range from 0 to 40 and higher scores indicate more symptoms.

Social Connectedness: The Social and Community Opportunities Profile (SCOPE Short) is a measure of social connectedness (inclusion, participation, citizenship) (35). In a recent systematic review (36), the SCOPE-Short was the measure with the best evidence of sound psychometric properties and covering the breadth of the construct of social inclusion for adults with a learning disability.

Loneliness and social satisfaction: The Modified Worker Loneliness Scale is a 12-item questionnaire that measures loneliness in adults with a learning disability. It has been used in several learning disability interventions and found to have good psychometric properties (37).

WHO Wellbeing 5: A short 5-item scale to measure subjective wellbeing (38).

Service Use and Costs: The study specific Client Receipt Services Inventory (39) will be used to collate service use and costs for people with a learning disability over the 12 months of the study for the preceding 6 months at each follow up point. It will be completed by the adult with a learning disability and their family/paid carer.

EQ-5D-Y (40): This questionnaire has simplified wording and has been used previously in adults with a learning disability (Jahoda et al., 2017). It is a generic preference-based measure of health-related quality of life, which provides a description of health using five dimensions (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression) each with levels of severity.

Outcome measures for mentors:

Health Related Quality of Life: WHOQOL-Dis is a measure of quality of life developed by the WHO (33). This 26-item short version consists of four domains (physical health, psychological health, social relationships, and environment QOL).

Psychological well-being and quality of life: The Warwick Edinburgh mental wellbeing scale (WEMWBS) (41) is a 14-item questionnaire that measures psychological well-being and quality of life in the adult general population.

Attitudes Towards People with a learning Disability: The 67-item Attitudes Towards Learning Disability Questionnaire (cognitive, affective, and behavioural components) (42).

EQ-5D-Y (40): This is a generic preference-based measure of health-related quality of life, which provides three a description of health using five dimensions (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression) each with levels of severity.

Outcome measures for family carers:

Health Related Quality of Life: WHOQOL-Dis is a measure of quality of life developed by the WHO (33). This 26-item short version consists of four domains (physical health, psychological health, social relationships, and environment QOL).

Psychological well-being and quality of life: The Warwick Edinburgh mental wellbeing scale (WEMWBS) (41) is a 14-item questionnaire that measures psychological well-being and quality of life in the adult general population.

EQ-5D-Y (40): This is a generic preference-based measure of health-related quality of life, which provides three a description of health using five dimensions (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression) each with levels of severity.

9 Screening, Consent and Recruitment

9.1 Screening & Recruitment strategy

Posters and flyers will be used to recruit potential local community groups and mentors in each site. The campaign will be run by the mainstream Volunteer Now organisation in Northern Ireland and Camden & Islington Foundation Trust volunteer service in London. A Volunteer Co-ordinator will be appointed to each site and based in each of these organisations. The Volunteer Co-ordinator will provide information and awareness raising sessions to those local community groups interested on the aim and purpose of the Matilda project; answering any questions the groups may have and meeting potential mentors. People interested in being mentors in the study will be asked to complete an application form to ensure they meet the inclusion criteria and attend an informal interview with the Volunteer Co-ordinator. When written consent has been obtained, the research staff will arrange to undertake the baseline measurements within two weeks.

Mentor training will be delivered by the Volunteer Co-ordinator in each site and will cover background to the Matilda project and the role of the mentor, disability awareness training, working with adults with learning disability, communication strategies and safeguarding training (incl. confidentially, identifying signs of abuse, managing behaviours that challenge, lone working). This group training will last 6 hours (one day or two-half days) and mentors will be provided with tea/coffee and lunch. The mentors will also receive monthly supervision from the Volunteer Co-ordinator in each site either face-to-face, by telephone or online to ensure the safety/wellbeing of the adult with a learning disability and check the fidelity of the intervention.

In Northern Ireland, we will work very closely with Volunteer Now. Volunteer Now is the lead organisation for promoting and supporting volunteering across Northern Ireland. It supports local community groups and voluntary organisations through the provision of training, promoting their volunteering opportunities, support with safeguarding, etc. Volunteer Now supports more than 40 mainstream older people community groups across the NHSCT such as Men's Shed, Knit and Knatter, recreational

groups (i.e., bowling), etc. They have access to approximately 3000 older adults without a learning disability who are registered volunteers in the NHSCT area who could be potential mentors for the Matilda project. Volunteer Now will recruit the Volunteer Co-ordinator, identify, and recruit the local community groups and the mentors, and provide the training and supervision for the mentors for the course of the Matilda project. Volunteer Now will work closely with the research team and the Volunteer Co-ordinator in the Camden & Islington Foundation Trust Volunteer Service, London.

In London, we will work with the Camden & Islington Foundation Trust volunteer service who will advertise and recruit the Volunteer Co-ordinator, identify the local community groups and mentors, and provide the training and supervision of the mentors. Part of the Camden & Islington Foundation Trust Volunteer Service includes a section for Activity Support and Befriending Volunteers (Services for Ageing Mental Health). The leader of the Camden & Islington Foundation Trust Volunteer Service will work closely with Volunteer Now to ensure the uniformity of the training, monitoring and supervisory arrangements across the two sites.

We will work closely with the NHSCT and the Camden Learning Disability Action Team who will facilitate the liaison between mentors and older people with a learning disability. These approaches in Northern Ireland and London are well-tested and are robust enough to support the trial.

Intervention development

9.2 Informed consent procedure

The study will be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki. It is the responsibility of the PI (designee RA in each clinical site) to obtain written informed consent from each participant before entry into the trial. The designee taking informed consent must be GCP trained, suitably qualified and experienced and have been delegated this duty by the PI on the delegation log. Appropriate signatures and dates must be obtained on the consent documentation prior to collection of trial data and the provision of the intervention.

According to the Mental Capacity Act (26) it is often wrongly assumed that all people with a learning disability do not have the mental capacity to make decisions of their own. Instead, it must be assumed that an adult with a learning disability has the capacity until proven otherwise. Therefore, it is important that the person is given the information required in a user-friendly format to make an informed decision using reasonable adjustments. We plan to manage on-going consent including assessment of capacity to consent using the following steps.

1. In addition to the usual requirements for consent training, the RAs will receive specific training at each site in how to assess capacity to consent and ensure informed consent is maintained throughout the project on a case-by-case basis. This training will involve how to enhance their communication skills, supplemented with user-friendly information (participant information sheet (PIS), consent form and questionnaires) supported by visual aids, to assess the person's decision-making capacity and understanding of trial participation to fulfil the tenets of capacity legislation in the three jurisdictions.

2. All participants will receive an easy read PIS and consent form with pictures or symbols to explain the purpose of the study and what is involved. The PIS and consent form have been prepared in collaboration with our PPI representatives.

3. The RAs will clearly explain the decisions to be made about joining the Matilda Project, completing some questionnaires at several time points, being randomised to either the intervention or control arm, and taking part in the process evaluation interview (qualitative study) using the user-friendly PIS or additional media or communication aids if required. The RAs will explain what is involved in participating in the Matilda Intervention (joining a community group, being matched to two or three mentors within the group, time commitments) and being randomised to the control group.

4. The RAs will assess if the person can retain the information and weigh up the pros and cons of making the decision to participate in study. The RAs will allow plenty of time to communicate with the person with the learning disability and check they can retain this information.

5. The RA will ask for a family member or advocate who is familiar with the communication needs of the person with the learning disability to be present during the interview, where appropriate.

6. The RAs will undertake the GCP course before being added to the delegation log. Assurance of on-going consent will be sought on a continual basis through the routine interactions with the RAs and individuals with a learning disability.

9.3 Withdrawal of consent

Participants may withdraw or be withdrawn from the study at any time without prejudice.

In the event of a request to withdraw from the study, the researcher will determine which elements of the study are to be withdrawn from, given the following possibilities. This will be documented.

- Continuation of the Matilda Intervention
- Process Evaluation
- On-going data collection
- Contact for follow-up questionnaires

If the request is to withdraw from all elements of the study, only anonymised data recorded up to the point of withdrawal will be included in the study analysis.

10 SCHEDULE OF ASSESSMENT

10.1 **Adults with Learning Disability Assessments**

All participants recruited to the trial must be evaluated according to the schedule of assessments described. Data will be collected as detailed at each timepoint stated below.

Study Visits and Procedures

Baseline

- Demographics (Date of birth, Gender, Ethnicity)
- Living Status (Where do you live, who do you live with?)
- Carer Information
- Medications
- Medical History (Health conditions)
- Questionnaires (WHOQOL, Glasgow Depression Scale, Social Connectedness, Loneliness Scale, WHO 5, EQ-5D-Y, CSRI).

6 months after randomisation

- Living Status (Where do you live, who do you live with?)
- Carer Information
- Medications
- Medical History (Health conditions)
- Questionnaires (WHOQOL, Glasgow Depression Scale, Social Connectedness, Loneliness Scale, WHO 5, EQ-5D-Y, CSRI).

12 months after randomisation

- Living Status (Where do you live, who do you live with?)
- Carer Information
- Medications
- Medical History (Health conditions)
- Questionnaires (WHOQOL, Glasgow Depression Scale, Social Connectedness, Loneliness Scale, WHO 5, EQ-5D-Y, CSRI).

10.2 **Mentors Assessments**

Baseline

- Demographics (Date of birth, Gender, Ethnicity)
- Living Status (Where do you live, who do you live with?)
- Questionnaires (WHOQOL, Warwick WB Scale, Attitudes towards people with a learning disability, EQ-5D-Y).

6 months after randomisation

- Living Status (Where do you live, who do you live with?)
- Questionnaires (WHOQOL, Warwick WB Scale, Attitudes towards people with a learning disability, EQ-5D-Y).

12 months after randomisation

- Living Status (Where do you live, who do you live with?)
- Questionnaires (WHOQOL, Warwick WB Scale, Attitudes towards people with a learning disability, EQ-5D-Y).

10.3 **Family Carer Assessments**

Baseline

- Demographics (Date of birth, Gender, Ethnicity)
- Living Status (Where do you live, who do you live with?)
- Questionnaires (WHOQOL, Warwick WB Scale, EQ-5D-Y).

6 months after randomisation

- Living Status (Where do you live, who do you live with?)
- Questionnaires (WHOQOL, Warwick WB Scale, EQ-5D-Y).

12 months after randomisation

- Living Status (Where do you live, who do you live with?)
- Questionnaires (WHOQOL, Warwick WB Scale, EQ-5D-Y).

10.4 **Process Evaluation**

The process evaluation 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. The process evaluation will employ a mixed methods approach:

Recruitment, matching, adherence (how often the adults with a learning disability and mentors meet weekly over the 6 months) and reach will be recorded by the mentors using the weekly logs. This will be further explored during the focus groups with the participants in the process evaluation.

Intervention implementation and modifications will be recorded through the focus groups with the mentors exploring their engagement with the adults with a learning disability and key influences on implementation (perceptions of the relationship; barriers/enablers to implementation).

Intervention mechanisms, receipt and acceptability needed (incl. benefits and/or adverse effects or unintended consequences) will be recorded through the focus groups with all participants, as well as with the disability staff and Volunteer Co-ordinators. We will explore recruitment, acceptability of randomisation, appropriateness of the outcome measures, acceptability, and engagement of the adults with a learning disability and mentors in the groups and reasons for not engaging/drop-out.

The above data (on recruitment, intervention implementation and intervention mechanisms) will help inform the assessment of the feasibility of implementing Matilda within a larger trial. We will hold focus groups with staff and the managers of the community groups in both sites exploring the facilitating factors and barriers to the adoption of the Matilda intervention, willingness to participate in a later definitive randomised trial and consider what systems and structures might be needed to maintain the intervention over-time.

Increasingly, qualitative, or mixed methods are being used in process evaluations of feasibility studies to capture salient information to inform a future randomised trial (53). Quantitative methods will be used to assess recruitment rates, the numbers of adults with a learning disability and mentors matched, mentors' weekly logs and fidelity checks. The dosage and intensity of the persons' engagement with their local community group will also be analysed as part of the progression criteria.

O'Cathain et al. (54) identified four key areas that qualitative research can explore in a feasibility study: intervention, processes, outcomes, and measures. Their guidelines consist of 16 items within five domains: research questions, data collection, analysis, teamwork, and reporting. We will collect data on these five domains using focus groups involving 20 older adults with a learning disability (10 from Northern Ireland and 10 from London), their family carers and mentors. We will explore the feasibility outcomes (recruitment, trial procedures, randomisation, mentors training and supervision) and clinical outcomes (acceptability of measures, benefits, and challenges with delivering the Matilda project) and what needs modifying. Where possible, we will also try and interview adults with a learning disability and their mentors who drop out of the study. We will ask some questions to the participants during the focus groups to determine how satisfied they were with the Matilda intervention and whether they would recommend it to a friend. We will also ask some questions about the appropriateness of the outcome measures, the ease of completion and time taken to complete them.

All participants will be invited to participate in the process evaluation. We will hold two focus groups of 6 to 8 adults with a learning disability who participated in the Matilda intervention in Northern Ireland and another focus group in London. We will hold two focus groups of 6 to 8 adults with a learning disability who participated in the control arm in both sites. There will be six focus groups with mentors, disability staff and the managers of the local community groups in both sites. In addition, we will hold two focus groups with family/paid carers who participated in the Matilda intervention in both sites. We will also follow-up with those adults with a learning disability and mentors who dropped out of the trial if they give us permission to do so. We will undertake maximum variation sampling of a representative group of participants (older adults with a learning disability, mentors, family carers) across both sites to participate in the process evaluation focus groups. If too many participants accept this invitation, we will randomly select participants to attend the focus groups and write to those who are not selected to thank them. These will be audio recorded and transcribed, stored via NVivo software and analysed using the 6-stage process by Braun and Clarke (2006) to facilitate the identification of sub/themes.

Trial Management Logs

We will collect information in the screening logs on how many eligible adults with a learning disability were randomised or the reasons for exclusion of those who were assessed for eligibility.

Fidelity of Intervention

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 a learning 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.

With volunteer-delivered interventions, there is the potential of a harmful effect when the programme ends with the person with disabilities being left feeling distressed; but this negative impact has been reported to be short lived. We will ensure during the consent process that all the participants understand that the intervention will only last for 6 months. In training the mentors, we will incorporate the guidance developed by Heslop (2005) on good practice in befriending services for people with a learning disability. The learning disability staff and Volunteer Co-ordinators will offer support to the person with a learning disability and mentors (meetings, phone calls) in preparation for the end of the intervention. The disability staff can provide support and signpost the person with a learning disability for further support. If this study identifies detrimental effects for participants' health and wellbeing, this would be immediately reported to the TSC and may lead to the study being terminated. One surprising result of the original Australian study (Stancliffe et al. 2015) was that many of the older adults with a learning disability continued to attend the community group with their mentors and other members of the group after the study had ended. This sustained involvement in the community groups will be recorded in the process evaluation through the focus groups with the participants and reported to the TSC. In addition, we will be able to record this sustained involvement in the community groups at the 6- and 12-month follow-up.

We will measure the frequency of the delivery of the Matilda intervention monthly through the logs, process evaluation and acknowledge the variability of the groups. Where possible, all the adults with a learning disability allocated to the intervention arm will be afforded the opportunity to access a group for the full 6 months. There may be occasions where some adults with a learning disability do not access their group, and this will be explored recorded and reported to the TSC.

10.5 Participant Follow-up & Procedures

As a token of gratitude and to encourage completion of the measures, the adults with a learning disability and their mentors will each be offered a financial incentive of a £10 voucher at each of the three time points. A £10 payment will be given to each adult with a learning disability in the intervention arm to recompense them for their time spent on completing the research measures at each of the three time points (not the intervention itself). Similarly, a £10 payment will be given to each adult with a learning disability in the control arm to recompense them for their time spent on completing the research measures at each of the three time points.

Participants will be asked to let the research team know if their contact details change or they move house at any time following recruitment to the study.

11 Data Collection and Data Management

11.1 Data Collection

To ensure accurate, complete, and reliable data are collected, the Chief Investigator will provide training to RA staff.

All data collection forms will be paper case report forms (CRFs) and data will manually be uploaded to a clinical database by the research staff at each site. Completed CRFs will be held at each site. Identification of participants will be through their unique participant study number, allocated at the time of randomisation. Data will be collected and recorded on the paper CRF by the RA as agreed for each site.

11.2 Data Quality

The Chief Investigator will provide training to the RA staff on trial processes and procedures including CRF completion and data collection. Data are to be entered onto the electronic database as per the CRF entry timelines.

On-site or remote monitoring visits during the trial will check; the accuracy of the data entered onto the CRF, entries against source documents alongside adherence to the protocol, trial specific procedures and GCP.

Changes to data will be recorded and fully auditable. Data errors will be documented, and corrective actions implemented.

Data validation will be implemented, and discrepancy reports will be generated following data entry to identify data that may be out of range or inconsistent, or protocol deviations, based on data validation checks programmed into the clinical trial database.

11.3 Data Management

The PI (or designee) at each site will collect all data and record this in the CRF. Each participant will be allocated a unique Participant Study Number at trial entry, and this will be used to identify the participant on the CRF for the duration of the trial.

Data will be collected from the time of trial entry. Trial data will be entered onto a CRF and processed electronically. Data queries will be raised via e-mail. Where clarification from site staff is required for data validations or missing data, site staff will respond to data queries ensuring that amendments are made as required.

12 STATISTICAL METHODS

12.1 Sample Size

Sample size for adults with a learning disability: Sixty-four individuals will be allocated using a 1:1 ratio, to one of two arms. The number selected is partly on pragmatic grounds but is also grounded in the need to obtain enough information to establish information on (a) recruitment, (b) intra-class and inter-class correlations, (c) item correlations and measures of central tendency and variability and (d) fidelity. The targeted recruitment rate is based on our experience in earlier studies, and we are confident that it can be achieved. In order to recruit 64 participants, we estimate that we will need to approach 100 adults with a learning disability. This is a conservative estimate based on several earlier feasibility trials for adults with a learning disability, which showed that only 30% to 40% more participants need to be approached to reach the desired sample size (Florides, 2012; Taggart et al., 2017). Other learning disability randomised trials have reported lower recruitment figures between 15% to 25% but our recruitment rate will allow us greater flexibility for sample matching, refusals, and dropouts.

Sample size for mentors: Based on the sample size of 32 adults with a learning disability in the intervention arm, each requiring 2-3 mentors, we estimate we will need 64-96 mentors. Also, bearing in mind that the Florides (2012) volunteer study on young adults with a learning disability found that 40% of the volunteers dropped out before the intervention started, we would need to approach 90 to 134 volunteers. Volunteer Now in Northern Ireland supports more than 40 mainstream older people community groups and have access to approximately 3000 older adults without a learning disability who are registered volunteers in the NHSCT area, who could be potential mentors for the Matilda project. These figures are similar for Camden & Islington Foundation Trust.

12.2 **Data Analysis**

Exploratory statistical analysis: When the data have been obtained, a range of descriptive statistics will be used to examine the results at both the level of the individuals, as they transition across the various points in time, and the summary condition. These will include summary statistics relating to trial groups. For example, means, medians, variances (interquartile range), percentages and count information will be examined. While formal statistical tests will not be reported, we will report confidence intervals (CIs), variances and covariance within and between conditions.

WHOQOL: The WHOQOL-Dis contains information from a field trial of 2614 individuals with physical disabilities (PD) and 1158 individuals with a learning disability (33). On looking across the 24 items, within the domains of (a) physical health, (b) psychological health, (c) social relationships and (d) environment, it is evident that those with a learning disability consistently have a lower mean score, and lower standard deviations. From an examination of the reported values of the skewness and kurtosis, the responses are well distributed in terms of normality.

Statistical power: In the field trial, the overall average score on the three social relationship questions was 2.36 for those classified as having a learning disability, while those classified as having a physical disability had a value of 3.34 (33). This difference of 0.98 was somewhat larger than the overall difference reported in the WHOQOL manual (0.6). This minimum important difference (MID) and the related standard deviations could be used to inform the sample size in the definitive trial. For example, a 2-group randomised trial with a desired power of 0.9, and an alpha value of 0.05, for a repeated measures ANOVA (2x3 mixed design) where a balanced design was implemented, would need 422 participants. For the purpose of this experiment, the correlation between the repeated measures was taken as 0.3, and the overall variance from the WHOQOL a learning disability module was used. The means were kept identical in the control group and linearly increased in the intervention condition. The power analysis was performed using Stata (45). These figures are based on a cross-sectional study, so caution is required, and part of this caution is the reason for the proposed feasibility study.

Target effect size and MCID: Based on the information above, the effect size is 1.09 points on the WHOQOL, having used a pooled standard deviation of 0.9. Should an effect of this size be present would the proposed feasibility study provide preliminary evidence of efficacy? Bell et al. (2018) (46) have proposed the use of CIs to inform this question. With an effect size of 1.09, the 95% CI is 0.86 to 1.32. This CI contains the MID (0.98) and would indicate that the intervention is performing as expected. For the purpose of sensitivity, the 80% confidence interval was also obtained: and is 0.94 to 1.24, as suggested by Browne (47) when using a pilot study for sample size determinations. Both sets of results indicate that the proposed feasibility study can achieve its object of providing preliminary evidence for the efficacy of the intervention.

Minimal clinically important difference (MCID): This can be obtained using the information from the above sources, since they relate to patient perception. The pooled standard deviation is used as an estimate for the baseline value in the current context in order to keep the comparison in a similar metric. The pooled standard deviation for the social domain measures (WHOQOL a learning disability module) is therefore 0.90 (as was used for the calculation for the MID and effect size), and the test-retest correlation (r) between the measures in the simulation was 0.5. From this information the standard error of measurement (SEM) can be obtained (SEM = SD*). The MCID has been proposed as 1*SEM, though a more stringent option of 1.96*SEM has also been suggested (i.e., less than 5% chance that the MCID value is within the expected random variability of the measure). In the current example, the MCID, using the more conventional criteria (MCID = 1*SEM), would correspond to a value = 0.64±0.23.

These calculations are based on a distribution-based method. When the pilot data becomes available, an anchor-based approach will also be employed using the WHOQOL measure where individuals will be plotted against a transition rate. The data will be separated by a horizontal line marking the MCID of the WHOQOL domain and a vertical line representing the MCID of the anchor point. Here the MCID will be derived as the value that maximises the sum of sensitivity and specificity.

Progression criteria: This pilot study will provide information that will be examined in the context of a definitive clinical trial. The primary outcome measure will be the social domain within the WHOQOL measure. The other domains within the WHOQOL will be examined as secondary outcome measures.

Several key indices will be used to determine the possible effectiveness of a definitive clinical trial. These will include an effect size of 1.09 having been obtained within the bounds of the CIs. A similar examination will be undertaken in relation to the minimum important difference. In the current context it is estimated that a MCID of 0.64 would indicate clinical importance. This distribution-based calculation will be cross-checked with the change in transitions across occasions. In the latter context, it is expected that most participating individuals should fall within the true positive quadrant.

12.3 **Health Economics Evaluation**

The economic evaluation will explore issues likely to be encountered in the conduct of a full economic appraisal including sources of data, how best to collect these and the inclusion of spill-over effects into the analysis. We will assess the feasibility of calculating quality adjusted life years (QALYs) using both the EQ5DY (48) and WHOQOL-DIS (33) and including spill-over effects experienced by mentors and family carers in the evaluation (49).

Costs of providing the intervention (including recruitment, training and expenses related to the supervision by the project manager) will be collected from the project manager in collaboration with participating sites. Information on resource use will be collected using an adapted version of the Client Service Receipt Inventory (39). Data will be collected at baseline, 6 and 12-months post-intervention. Resource utilization will cover the period since the last data collection point at 6 and 12 months: and in the previous 6 months in the case of baseline measurement. Health and social care use will include contacts with health professionals such as GPs, psychiatrists, psychologists, community nurses, social workers, and community learning disability teams as well as use of hospital accident and emergency, inpatient and outpatient services. Information on prescription of medicines will also be collected.

Resource use will be monetised using published sources, PSSRU (50), NHS reference costs (51) and the British National Formulary (52). Costs will be reported from a health and social care perspective. In the base case analysis, we will focus on

costs and outcomes as they accrue to the participant with a learning disability only. Total costs in each randomised group will be compared using a Generalised Linear Regression Model as costs are likely to be non-zero and positively skewed.

We will explore estimation of the incremental mean cost per QALY gained from the intervention compared to the control group and the cost-effectiveness of the intervention across other outcome measures. If calculable the mean QALY per participant with a learning disability will be calculated as the area under the curve for the duration of the trial, adjusting for baseline values. CIs will be constructed using non-parametric bootstrapping with replacement. This exercise will be explored for outcome measures generated using EQ5D if possible and cost-effectiveness using WHOQOL-DISF.

To explore potential spill-over effects among mentors and family carers, these groups will also complete health-related quality of life questionnaires (as above). These will be completed at the same time points as participants with a learning disability and an area under the curve approach with adjustment for baseline values used to estimate the change in health-related quality of life. This data will be used to calculate multipliers – one for health benefits of providing the intervention and one for health benefits displaced by the intervention as detailed in Al-Janabi et al. (2016). These capture the potential spill-over effects associated with the intervention as the ratio of total health effects to participant with a learning disability health effects. Consistent with Al-Janabi et al. (2016) these will be used to estimate the impact on funding guidance associated with the inclusion of spill-over effects. In sensitivity analysis the extension of spill over effects across multiple mentors and family carers will be explored.

12.4 **Missing data**

It is expected that some participants who provide baseline information will not remain with the study. Where information is available for the baseline assessment, but missing on some other occasion, the person will remain within the analysis. This is based on an intention to treat principle, and we will examine the exploratory results using various imputation methods and statistical modelling strategies. These will be employed throughout the exploratory data analysis and confidence intervals will be evaluated and reported. This analysis of missing data will provide useful information regarding the estimation of statistical power for a definitive trial, through a process of statistical simulations.

13 SAFETY REPORTING

13.1 **Adverse Event (AE) / Serious Adverse Event (SAE) Reporting**

As the study involves a low-risk intervention, we would not expect any adverse events (AE) arising from the Matilda intervention. As such, AE reporting will follow the Health Research Authority (HRA) guidelines on safety reporting for non-clinical trials as outlined below.

Participants will be encouraged to let the study team know about AEs at each visit. AEs will not be reportable events. However, if an AE is deemed to be serious (based on the definition below), then the Serious Adverse Event (SAE) should be reported to the research team. A SAE Form should be completed by the PI or designee and submitted within 24 hours of becoming aware of the event.

The AE reporting period begins upon enrolment of the participant into the trial and ends 14 days after the last day of the delivery of the intervention.

Further information is provided in the Matilda Intervention ‘Safety Reporting Guideline’.

13.2 **Assessment of Seriousness**

The PI or designee at each site should make an assessment of seriousness. A serious adverse event is an adverse event on the basis that it:

- Resulted in death
- Is life-threatening
- Requires hospitalisation or prolongation of existing hospitalisation
- Results in persistent or significant disability or incapacity
- Is otherwise considered medically significant by the investigator

Hospitalisation is defined as an inpatient admission regardless of length of stay, even if the hospitalisation is a precautionary measure for continued observation. Hospitalisations for a pre-existing condition, including elective procedures that have not worsened, do not constitute a SAE.

13.3 **Assessment of Causality and Expectedness**

The PI or designee at each site will co-ordinate the assessment of the SAE for causality and expectedness by a delegated member of the study team. The assessment of causality in relation to the Matilda intervention will be undertaken using the definitions in Table 4

Table 4: Serious Adverse Event (SAE) causality definitions

Causality assessment	Description
Unrelated	There is no evidence of or rationale for any causal relationship.
Likely to be related	There is evidence, and a rationale, to suggest a causal relationship and other possible contributing factors can be ruled out.

As there are no expected AEs for this study, all serious adverse events will be considered unexpected. Therefore, the event will be classified as a Suspected Unexpected Serious Adverse Reaction (SUSAR) if the SAE occurring to a research participant is deemed to be:

- *Related*: that is, it resulted from delivery of the intervention (see Table 4), **and**
- *Unexpected*: that is, the type of event not listed in the protocol as an expected occurrence

The CI will be responsible for reporting the SUSAR to the Sponsor and to the REC which issued the favourable ethical opinion. The CI will submit the SAE (using the SAE report for non-CTIMPs published on the Health Research Authority website) within 15 days of becoming aware of the event.

13.4 Urgent Safety Measures

If the PI at a site becomes aware of information that necessitates an immediate change in study procedure to protect research participants from any immediate hazard, they can implement this immediately and before approval by the REC.

If an urgent safety measure is taken, the PI should notify the CI within 24 hours (via email to l.taggart@ulster.ac.uk), setting out the reasons for the urgent safety measure.

The PI will notify the CI who will liaise with Sponsor and REC. The CI will notify the REC providing full details of the information they have received and the decision-making process leading to the implementation of the urgent safety measure within 3 days.

14 DATA MONITORING

14.1 Data access

The agreement with each PI will include permission for trial related monitoring, audits, ethics committee review and regulatory inspections, by providing direct access to source data and trial related documentation. Agreement / consent from participants for this will also be obtained.

Each participant's confidentiality will be maintained and will not be made publicly available to the extent permitted by the applicable laws and regulations.

All essential documentation i.e., the Investigator Site file (ISF) and source data will be stored by sites. The TMF and associated trial data will be stored by the CI in conformance with the applicable regulatory requirements and access to stored information will be restricted to authorised personnel. Following the publication of the primary and secondary study outcomes, there may be scope for the CI and others in the study to conduct additional analyses on the data collected. In the event of publications arising from such analyses, those responsible will need to provide the CI with a copy of any intended manuscript for approval prior to submission.

14.2 Monitoring arrangements

The CI will be responsible for trial monitoring. On-site/Remote monitoring visits will be conducted in accordance with the trial monitoring plan. Monitoring will be an on-going activity from the time of initiation until trial close-out and will comply with the principles of GCP. The frequency and type of monitoring will be detailed in the monitoring plan and agreed by the Sponsor.

Before the trial starts at a participating site, an initiation meeting will take place to ensure that site staff are fully aware of the trial protocol and procedures. Checks will take place to ensure all relevant essential documents and trial supplies are in place. On-site or remote monitoring visits during the trial will check the accuracy of data entered into the CRF against the source documents, adherence to the protocol, procedures and GCP, and the progress of recruitment and follow up.

The PI or designee should ensure that access to all trial related documents (including source documents) are available during monitoring visits. The extent of source data verification (SDV) will be documented in the monitoring plan.

15 REGULATIONS, ETHICS AND GOVERNANCE

15.1 Sponsorship

The Ulster University will act as sponsor for the study. Sub-contracts delegating responsibilities to research sites will be established using our standard contracting processes with NHS organisations.

15.2 Regulatory and Ethical Approvals

The Matilda trial is not a clinical trial of an investigational medicinal product, and thus is not governed by the Medicines for Human Use (Clinical Trials) Regulations 2004.

The trial will require REC approval and NHS permission. The ethics application made by the CI will cover all collaborating sites. The application to the REC and the relevant NHS R&D offices will be made through the Integrated Research Application System (IRAS).

The trial protocol was prepared in compliance with the SPIRIT 2013 statement. The trial will be prospectively registered.

15.3 Protocol Compliance

The investigators will conduct the study in compliance with the protocol given approval/favourable opinion by the Ethics Committee. Protocol compliance will be monitored by the trial monitor at site visits. Any deviations from the protocol will be fully documented in in the CRF.

15.4 Protocol Amendments

All protocol amendments will be undertaken in accordance with the regulatory requirements. Substantial changes to the protocol will require ethics committee approval/favourable opinion prior to implementation, except when modification is needed to eliminate any immediate hazards to individuals.

15.5 Good Clinical Practice

The study will be conducted in accordance with the ethical principles originating in the Declaration of Helsinki, those in the Medical Research Council's Good Clinical Practice and the Department of Health's Research Governance Framework

15.6 Indemnity

The Ulster University will provide indemnity for any negligent harm caused to participants by the design of the research protocol.

15.7 Participants' Confidentiality

To maintain confidentiality, all CRFs, questionnaires, study reports and communication regarding the study will identify the individuals by their assigned unique study identifier and initials only. Confidentiality will be maintained at every stage and identifying information for individual participants will not be made publicly available to the extent permitted by the applicable laws and regulations.

15.8 Record Retention

Archiving of essential documents will take place as outlined in the Sponsor Delegation Framework.

The site PI will be provided with an ISF by the CI and will maintain all trial records according to GCP and the applicable regulatory requirements. The PI is responsible for archiving of essential documents at their site in accordance with the requirements of the applicable regulatory requirements, Sponsor, and local policies. The PI has a responsibility to allow Sponsor access to archived data and can be audited by the Sponsor on request. Following confirmation from the Sponsor who will notify the PI when they are no longer required to maintain the files. If the PI withdraws from the responsibility of keeping the trial records, custody must be transferred to a person willing to accept responsibility and this must be documented in writing to the and Sponsor.

The TMF will be held by the CI and the essential documents that make up the TMF will be listed in an. On completion of the trial, the TMF and study data will be archived by the CI according to the applicable regulatory requirements and as required by the UU Sponsor.

15.9 Competing Interests

The NIHR HTA funds the research costs. The CI and members of the TMG have no financial or non-financial competing interests and the members of the TSC will be asked to confirm that they have no conflicts of interest. In the event that a TSC member reports a conflict of interest, advice will be sought from the Sponsor and the Funder.

16 DISSEMINATION/PUBLICATIONS

16.1 Publication Policy

We plan to publish our trial protocol and statistical analysis plan to ensure transparency in our methodology. Long-term data will also be reported, although may form the basis of separate publications.

The study findings will be submitted for publication in peer-reviewed journals and for presentation at appropriate national and international conferences. Presentation at these meetings will ensure that results and any implications quickly reach the disability and older person communities.

A lay person's summary of the principal findings of the results will be sent to all individuals involved in the study at their request. An on-going update of the trial will also be provided on the Ulster University website.

16.2 Authorship Policy

Authorship will be determined according to the internationally agreed criteria for authorship recommended by the International Committee of Medical Journal Editors (ICMJE). Authorship of parallel studies initiated outside of the TMG will be according to individuals involved in the project but must acknowledge the contribution of the TMG.

16.3 Data Sharing Statement

The study will comply with the good practice principles for sharing individual participant data from publicly funded clinical trials and data sharing will be undertaken in accordance with the required regulatory requirements. Requests for data sharing will be reviewed on an individual basis by the CI.

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