Priment™ Clinical Trials Unit

Pilot randomised controlled trial of one to one befriending by volunteers, compared to Usual Care, in reducing symptoms of depression in people with intellectual disability

PROTOCOL

Long title of the trial	A pilot randomised controlled trial of one to one befriending by volunteers, compared to Usual Care, in reducing symptoms of depression in people with intellectual disability (ID)
Short title of trial	Befriending in people with ID (BID trial)
Version and date of protocol	Draft Version 1, [27/04/2018]
Sponsor	UCL
Sponsor protocol number	
Funder (s)	Public Health Research Funding Stream of NIHR
Trial registration number	
EudraCT number	
Phase of trial	Phase II
Sites	Multi site (2 sites)
Chief investigator:	Dr Afia Ali afia.ali@ucl.ac.uk
Sponsor Representative:	Jessica Broni-Tabi Jessica.broni-tabi@nhs.net.

SIGNATURES

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the trial in compliance with the approved protocol and will adhere to the principles of GCP the Sponsor's SOPs, and other regulatory requirements as amended.

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

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

Chief Investigator: Afia Ali

Sign: 

Date: 23/11/2018

Sponsor Representative: UCL- Jessica Broni-Tabi

Sign: 

Date: 29/11/2018

For the purposes of this document, Priment is representing the Sponsor.

This Protocol template is intended for use with UK sites only.

VERSION HISTORY

Version number	Version date	Reason for Change
1	27/04/2018	

1 TABLE OF CONTENTS

2 LIST OF ABBREVIATIONS

Term	Definition
AE	Adverse Event
AR	Adverse Reaction
ATTID	Attitudes Towards Intellectual Disability Questionnaire
CBT	Cognitive Behaviour Therapy
CI	Chief Investigator
CRF	Case Report Form
CSRI	Client Services receipt Inventory
DPA	Data Protection Act 2018
Non-CTIMP	Clinical Trial without an Investigational Medicinal Product
EQ-5D-Y	EuroQol-Youth
GAfREC	Governance Arrangements for NHS Research Ethics
GCP	Good Clinical Practice
GCPLA	Guernsey Community Participation and Leisure Assessment
GDPR	General Data Protection Regulations
GDS-LD	The Glasgow Depression Scale for people with a Learning Disability
HRA	Health Research Authority
ICF	Informed Consent Form
ID	Intellectual Disability
IQ	Intelligence Quotient
ISF	Investigator Site File
ISRCTN	International Standard Randomised Controlled Trials Number
Main REC	Main Research Ethics Committee
MANS-LD	Maslow Assessment of Needs Scale-Learning Disability
MWLQ	Modified Worker Loneliness Questionnaire
NHS R&D	National Health Service Research & Development
PI	Principal Investigator
PIS	Participant Information Sheet
PPI	Patient Public Invovlement
QA	Quality Assurance
QALY	Quality Adjusted Life
QC	Quality Control
RCT	Randomised Control Trial
REC	Research Ethics Committee

SAE	Serious Adverse Event
SAR	Serious Adverse Reaction
SDV	Source Document Verification
SMD	Standardised Mean Differences
SOP	Standard Operating Procedure
SSA	Site Specific Assessment
SUSAR	Suspected Unexpected Serious Adverse Reaction
SSSR	Social Support Self Report for intellectually disabled adults (SSSR)
TMG	Trial Management Group
TRG	Trial Review Group
UCL	University College London
UCLA Loneliness Scale	University of California, Los Angeles loneliness scale
WASI	Wechsler Abbreviated Scale of Intelligence
WEMWBS	Warwick- Edinburgh mental wellbeing scale
WHO-QOL-8	World Health Organisation Quality of Life questionnaire

3 TRIAL PERSONNEL

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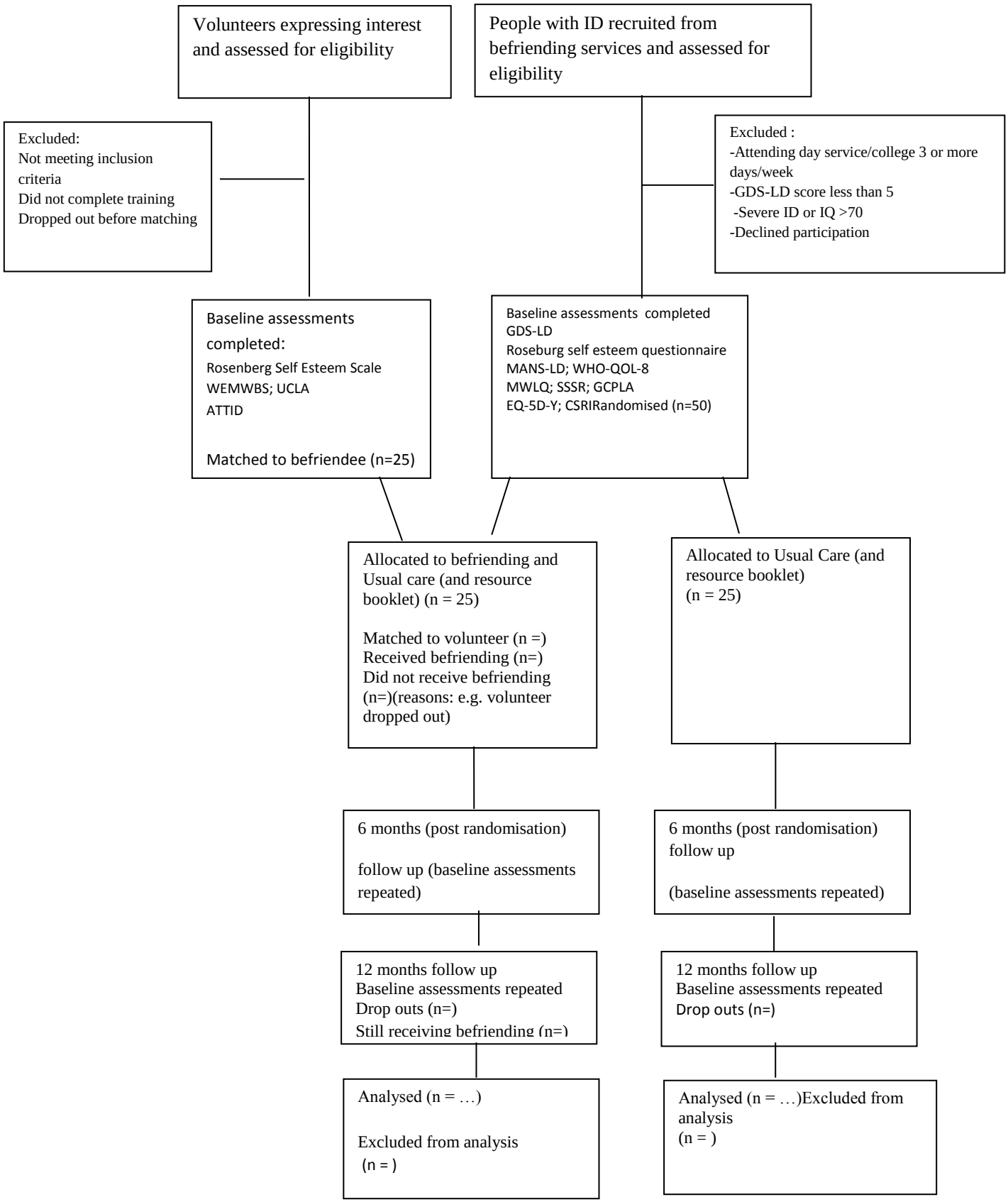
4 SUMMARY

Title:	A pilot randomised controlled trial of one to one befriending by volunteers, compared to Usual Care, in reducing symptoms of depression in people with intellectual disability (ID)
Short title:	Befriending in people with ID (BID trial)
Phase of trial:	Phase II
Objectives:	The primary objective is to assess the recruitment rate of individuals with ID and volunteers, the number of successfully matched pairs and the drop-out rate of individuals with ID and volunteers. The secondary objectives of the study are to: 1. Measure adherence to the trial protocol including delivery of intervention, training and supervision of volunteers 2. Explore the views of stakeholders about the acceptability of the intervention and trial procedures 3. Investigate the appropriateness of the outcome measures 4. Estimate the effect of befriending on the primary and secondary outcomes 5. Estimate the sample size required for a full scale randomised controlled trial 6. Make a preliminary investigation of the cost-effectiveness of the befriending intervention
Type of trial:	A pilot, single-blind, randomised, parallel group, multisite trial in people with ID
Trial design and methods:	Intervention: Participants will be matched to a volunteer who will meet with the individual at least once a week over a six month period. They will be given a booklet of local resources. Control arm: Booklet of local resources only. Both groups will have access to Usual Care, which will include contact with health and social care professionals within primary care and intellectual disability services, pharmacological and psychological treatments and day services. Outcomes: Feasibility outcomes (primary outcome): recruitment and drop-out rates; Health and economic outcomes (secondary outcomes):

	symptoms of depression at 12 months; self-esteem, quality of life, loneliness, social support, social participation, health related quality of life and service use costs. Outcomes will be recorded at baseline, end of the intervention (6 months), and at 12 months. In volunteers, self-esteem, emotional well-being, loneliness and attitudes towards people with ID before matching and at six and 12 months will be measured.
Trial duration per participant:	13 months
Estimated total trial duration:	18 months
Planned trial sites:	Multisite (2 sites)
Total number of participants planned:	50 participants with ID and 25 volunteers
Main inclusion/exclusion criteria:	Individuals aged 18 or over with mild or moderate ID (IQ 35 – 69), who have a score of 5 or more on the GDS-LD, not attending education/ day service for more than two days a week, will be recruited from referrals to befriending organisations and community ID services. Exclusion criteria: severe ID (IQ below 35), unable to communicate in English or provide consent. Volunteers will be aged 18 and over and will be recruited by the befriending organisations in their usual way. Those with a criminal record will be excluded.
Statistical methodology and analysis:	The characteristics of participants by trial arm will be summarised using mean (SD) or medians (IQ range) for continuous variables and counts (percentage) for categorical variables. 1. Feasibility outcomes will be analysed using counts and proportions. 2. Appropriate regression models adjusted for baseline values will be used to estimate the intervention effect on health outcomes. Only estimates will be presented with corresponding 95% confidence intervals. All analyses will be carried out as allocated. 3. Health economics: Incremental cost per change in the primary outcome (depression scores on the GDS-LD) between the intervention and control group will be analysed. Cost per quality-adjusted life year (QALY) using the EuroQol-Youth (EQ-5D-Y), will be calculated.

5 TRIAL FLOW CHART

Flow diagram for Pilot randomised controlled trial of one to one befriending by volunteers for people with intellectual disability (ID)



6 INTRODUCTION

6.1 BACKGROUND

i. Why is this research important?

Intellectual disability (ID) is a life-long condition characterised by an Intelligence Quotient IQ below 70 and impaired adaptive functioning, arising before the age of 18 (1). The UK prevalence of ID is 1-2% (2). People with ID have complex health needs but experience substantial inequalities in health, including poorer access to health services, higher rates of physical heath disorders (3,4), higher mortality rates and die 20-25 years earlier than people in the general population(3,5). They have higher rates of mental illness, with a point prevalence of 41% (6,7) and the same or higher prevalence of depression compared to the general population, but they are more likely to experience chronic depression (8-9). People with ID have greater exposure to life events and social disadvantage (10), experience social exclusion because of stigma (11), have markedly smaller social networks (3.1 compared to 125) (12-13) and have a higher prevalence of loneliness compared to other people (14). These factors have been associated with depressive symptoms in this group (14, 15-18).

People with ID may experience behavioural side effects from antidepressant treatment (e.g. aggression and agitation, (19)) encounter inequalities in accessing psychological therapies (20), and the evidence base for the effectiveness of psychological treatments in depression for people with ID is limited (21). There is a need to consider alternative, accessible interventions in the management of depression. One such intervention that has shown some promise is befriending (22).

ii. Background and conceptualisation of befriending

Befriending is “a relationship between two or more individuals, initiated, supported and monitored by an agency. The relationship is non-judgmental, mutual, purposeful, and there is a commitment over time” (23). Key attributes of befriending are that it is a one to one friendship-like relationship, it is an organised intervention, and that there is a negotiation of power (24). There is a wide variation in the concept and practice of befriending (25). At one extreme, befriending is very close to a friendship, characterised as being reciprocal and equal, with both parties being comfortable in sharing personal information and is delivered by lay volunteers, and at the other end it as a professional and therapeutic relationship, focused on the befriendee attaining goals and aspirations, and is on a continuum with mentoring. Most types of befriending relationships lie midway on this spectrum and may involve listening and providing emotional support, but it may be prescriptive in terms of the length and duration of meetings, and there is usually discussion of boundaries around the sharing of personal information (25), from not sharing any personal details through to the befriendee being introduced to family or friends. Most schemes also offer training,

supervision and on-going support to volunteers. Befriending schemes are most often provided by voluntary organisations in the community.

iii. Theoretical underlining of befriending

Loneliness and social isolation are associated with increased physical and mental health morbidity and mortality (26-27). Befriending aims to help individuals who are lonely, isolated and have limited opportunities for social and community participation by increasing social and emotional support and by enhancing social networks and community participation. The causal mechanisms of befriending on health outcomes are unclear. However, social support is thought to be important. Social support has structural characteristics, in terms of the number and connectedness of social ties, and functional characteristics such as providing instrumental or emotional support, information and advice. Social support may improve mental health by acting as a buffer to stress or it may have an effect in the absence of pre-existing stress. There is evidence to suggest that it may mediate genetic and environmental vulnerabilities to depression through its effects on neurobiological factors and other psychosocial factors (e.g. coping strategies) (28). Perceived social support rather than received social support appears to be related to psychological wellbeing, and therefore providing support where it is not needed can be unhelpful (29). The main underlying assumption in befriending interventions is that providing an individual who is lonely and lacking in social networks, additional, enacted support through a befriender, will lead to an increase in the individual's level of perceived support, resulting in improved psychological wellbeing. Befriending may enhance social support by providing direct emotional and instrumental support, but also the befriender can help to link the befriendee into social activities, which may be sustainable outside of, and beyond the end of the befriending relationship, and therefore it may have longer term benefits. Befriending may also improve health outcomes thorough its effects on social networks (30).

6.2 PRECLINICAL DATA

N/A

6.3 CLINICAL DATA

Befriending (as an active control delivered by professionals) has been found to have similar effects to CBT (32) and Acceptance and Commitment Therapy in schizophrenia (33).There is evidence from a well conducted systematic review that befriending in people with mental or physical health problems (but not ID) may have a significant but modest effect on reducing symptoms of depression when compared to no treatment or treatment as usual in both the short and long term, with standardised mean differences (SMD) of -0.27 (95% Confidence Intervals: -0.48 to -0.06) and -0.18 (95% Confidence Intervals:-0.32 to -0.05) respectively (22). The review included studies of paid and unpaid volunteers and befriending delivered in various ways, including face to face and telephone contact. A recent review and meta-

analysis of befriending by unpaid volunteers, examined the effects of befriending on participants with physical and mental health disorders across a range of social and psychological outcome measures (34). Befriending was associated with better patient reported outcomes across all primary outcomes but the effect size was small (SMD of 0.18). There was limited evidence for the effectiveness of befriending on individual outcomes such as depression, loneliness or quality of life when the studies were combined (34). However, a number of individual studies did suggest that befriending had an impact on depression, wellbeing and social support.

6.4 RATIONALE AND RISKS/BENEFITS

There are no published RCTs of the impact of befriending on depressive symptoms in people with ID. One study has examined the effects of a "visiting service" on elderly widows and found that participants who had high levels of social isolation, two or more physical illnesses or who had low levels of education (no education or primary school only) responded well to the intervention, with effect sizes of between 0.54 and 0.63 for a reduction in depressive symptoms (p values < 0.05) (35). These characteristics are not dissimilar to those found in people with ID and therefore we could expect similar effect sizes in this population. Data on the cost-effectiveness of befriending is limited but one recent study suggests that befriending may be cost-effective (36).

V. Harmful effects of befriending

The effects of befriending may be short-lived and individuals may be adversely affected by the loss of their befriender at the end of the intervention (32). People with ID have reported feeling distressed following the termination of their befriending relationship (37). Other risks include the emotional turbulence that is associated with a natural friendship, or harmful effects if the befriender is not adequately trained or supervised. There may also be undue burden placed on the befriender to take on excessive responsibility (25). See section 6.5 for a description of risks associated with the trial and approaches to mitigating the risks.

VI. Benefits for volunteers and wider society

Befriending schemes may also benefit befrienders who gain greater awareness and empathy, feel rewarded by helping others and contributing to their community, and develop new skills and experience that improves employability (38). A systematic review and meta-analysis found that volunteering had beneficial effects on depression, psychological wellbeing and life satisfaction, and was associated with lower risk of mortality, although the causal mechanisms for these associations are unclear (39). The benefits to wider society include economic impacts such as reduced burden on government spending and improved employability of volunteers; strengthening of social connections between different sectors and organisations within the community; and safer, stronger and more

cohesive communities (e.g. inverse relationship between levels of volunteering and crime) (40).

Rationale for proposed research

Whilst the benefits of befriending have been explored in a range of disorders, its effectiveness in people with ID has not been evaluated in a randomised trial. A single arm feasibility study of one to one befriending by volunteers, conducted by a voluntary organisation, (38) recruited 24 volunteers, of which 15 were matched with an individual with ID. Sixty percent of the individuals with ID reported a positive change; 53% reported a decrease in isolation and 40% reported an increase in confidence.

One Australian study examined the feasibility of using active mentoring to improve the participation of older adults with ID in mainstream community groups (41). The intervention comprised 29 individuals receiving the intervention and a matched comparison group. The participants in the intervention reported better social satisfaction compared to the comparison group (effect size (Cohen's d): 0.78, p= 0.02). Symptoms of depression on the carer reported version of the Glasgow Depression Scale in People with Learning Disability (GDS-LD) were reduced but not statistically significantly (effect size (Cohen's d) 0.28, p = 0.86). The study found that the intervention was feasible and acceptable. However, the sample comprised older adults living in Australia, and the intervention is not directly comparable to one to one befriending.

Given the dearth of studies examining befriending in people with ID and insufficient data on feasibility, there is a clear rationale for carrying out a pilot study prior to a full randomised controlled trial.

6.5 ASSESSMENT AND MANAGEMENT OF RISK

The table below summarise the potential risks and mitigation of risks associated with the trial

Intervention	Potential risk	Risk Management
Befriending intervention	1. verbal/physical abuse directed towards volunteer	Risk assessments to be carried out prior to matching to ensure that the matching and environment (e.g. participant's home) is safe (See Section 11.6 iii

		for details on matching). Lone working policy to be followed. Behaviour contract to be completed by both parties.
	2. Abuse/ exploitation of the person with ID by volunteer	References and DBS checks on all potential volunteers. Training and supervision of volunteers throughout the intervention. Safeguarding procedures will be followed if risk occurs and training on safeguarding will be provided for volunteers (see section 11.6 iii for details on training).
	3. Person with ID becomes distressed when relationship with volunteer comes to an end.	Ensure person with ID and volunteer are aware that the relationship will end. Volunteer coordinator to provide support after relationship ends.
	4. Anxiety and stress resulting from the befriending relationship in both the person with ID and volunteer	Volunteers will have access to monthly supervision to discuss their concerns. Volunteer coordinator will contact individual with ID once a month. Volunteers and individuals with ID can drop out of the study at any time. They will be signposted to relevant support (e.g. GP, counselling).
Consent in persons with ID	Risk that the consent is not done in line with the requirements for consenting in vulnerable participants/ participants incapable of giving informed consent. People with ID may not be able to understand the information provided, risk being easily coerced into taking part or unable to articulate their thinking/reasoning	The PIS given to persons with ID will be with visual aids and written in a language they will likely understand, PPI involvement in the PIS will be sought and also will be reviewed and approved by an ethics committee. The capacity of an individual to

	adequately and thereby their rights and wellbeing of the population may not be adequately protected.	give informed consent will be assessed on a case-by-case basis, with careful consideration on how people who are members of the person's support network will be informed about the study to ensure that potential participants experience no coercion in making their decision about whether or not to take part in the study. In the event of any conflict between the person with ID and their support network, the person WILL NOT enter the study. Staff at sites will be suitably qualified, GCP trained and trained in taking consent in vulnerable populations.
Randomisation	Person with ID may be disappointed or distressed by not being randomised to receive the befriending intervention. They want or perceive they need. Risk of accidental unblinding of the research team by volunteer or participant with ID at follow up assessments.	Ensure during the consent process that the person with ID understands the intervention and control arm and that there is no choice which they will receive. Individuals with ID will be reminded prior to the assessment not to disclose details about their allocation. Volunteers will be requested not to reveal details about their match. If unblinding occurs, this will be documented. See section 11.4.
Outcomes	Risk of incomplete questionnaires/ failure to complete questionnaires	Use of validated questionnaires in people with ID and supporting individuals to complete the questionnaires. Excluding people with severe ID.
Recruitment	Failure to recruit sufficient numbers of volunteers to match with individuals with ID	Maximise recruitment of volunteers through different routes (market stalls, newspaper adverts, websites) with emphasis

		on potential benefits for volunteers.
Failure to protect privacy	Loss or breach of Sensitive/ personal data	Trial will be registered with the sponsor Data Protection Office Data Privacy Assessment will be carried out Data will be securely stored with restricted access. For data stored in Sealed Envelope, agreements will be in place to ensure that data is not processed by third parties. PIS will be transparent about who will have access to data Research staff handling data will be trained in GCP and GDPR.
	Breach in the boundaries between volunteers and persons with ID (e.g. sharing personal details, introducing person with ID to family members and friends).	Volunteers will receive training on professional boundaries and will receive a manual that provides guidance.

7 OBJECTIVES

Primary:

The primary objective is to determine the feasibility of a full scale randomised controlled trial of one to one befriending by volunteers for people with ID in addition to usual care, compared to a control arm comprising Usual Care and a booklet of community resources and amenities (which will also be given to the intervention arm). We will examine the recruitment rate of individuals with ID and volunteers, the number of successfully matched pairs within the six month study recruitment period,

and the subsequent drop-out rates of volunteers or individuals with ID at six and 12 months follow up.

Secondary:

1. Record any negative consequences/adverse effects of befriending including issues related to safeguarding and managing termination of relationships
2. Estimate the number of relationships that continue beyond 6 months
3. Measure adherence to the trial protocol including delivery of intervention, training and supervision of volunteers
4. Explore the views of individuals, volunteers, carers and befriending services about the acceptability of the intervention and trial procedures such as randomisation and completion of assessments at the different follow up periods
5. Investigate the appropriateness of the secondary outcome measures (rates of completion and time taken to complete measures, change in scores)
6. Estimate the effect of befriending on depression score at 12 months, psychological distress, self esteem, loneliness and outcomes in volunteers (e.g. wellbeing) at 6 and 12 months post randomisation.
7. Estimate the sample size required for a full scale randomised controlled trial
8. Make a preliminary investigation of the cost-effectiveness of the befriending intervention

8 OUTCOMES

8.1 PRIMARY OUTCOMES

The primary outcome will be the recruitment rate of volunteers and eligible participants with ID over a six months period; the number of matched pairs of volunteers and participants over a six month period; the number of people with ID and volunteers who drop out of the study and reasons why.

8.2 SECONDARY OUTCOMES

1. The main health outcome of interest is depressive symptoms at 12 months post randomisation. Depressive symptoms has been selected as the potential primary outcome for a future randomised clinical trial as current evidence suggests that this would be the most appropriate outcome for a befriending intervention, based on findings from a systematic review that depressive symptoms were reduced in the short and long term (24), and that befriending may be more effective in those who are very socially isolated or have poor educational attainment (35). Examining symptoms at 12 months will enable us to capture potential negative effects of relationships terminating at six months. Depressive symptoms will be measured using the GDS-LD (44) which has established psychometric properties and has been used in a number of trials of psychosocial interventions in people with ID. This is a 20 item self-report scale. Scores range from 0-40 and higher scores indicate

more symptoms. Depressive symptoms will also be assessed at 6 months (post randomisation), measured using the GDS-LD (42).

2. Self-esteem measured at 6 months and 12 months using the adapted Rosenberg self-esteem scale for people with intellectual disabilities (43), which is a self-report scale with 6 items and is a widely used, validated measure. This will be analysed as a continuous variable.

3. Quality of life at 6 months and 12 months using the Maslow Assessment of Needs Scale-Learning Disability (MANS-LD; (44)) and five items from the adapted World Health Organisation Quality of Life questionnaire (WHO-QOL-8; (45)). It will be analysed as a continuous variable.

4. Loneliness and social satisfaction at 6 months and 12 months will be measured using the self report, 12 item Modified Worker Loneliness Questionnaire (MWLQ (46), which has been validated in people with intellectual disability and has good psychometric properties. It will be analysed as a continuous variable.

5. Social support will be measured at 6 months and 12 months using the Social Support Self Report for intellectually disabled adults (SSSR) (47), which measures perceived social support from friends, family, staff and romantic partner on a three point scale. It will be analysed as a continuous variable.

6. Social participation will be measured at 6 months and 12 months using the Guernsey Community Participation and Leisure Assessment (GCPLA) (48). It contains six categories of activity relating to 49 operationally defined contacts. It will be used to measure the frequency of participation in community activities over the previous six month period. It will be analysed as a continuous variable.

7. Health related quality of life will be measured at 6 and 12 months using the EuroQol-Youth (EQ-5D-Y), which will be used to calculate Quality adjusted life years (QALYs) in line with accepted guidance (49). The EQ-5D-Y is a generic instrument containing 5 dimensions (mobility, looking after myself, doing usual activities, having pain or discomfort and feeling worried, sad or unhappy), 3 levels per dimension (no problems, some problems and a lot of problems) questionnaire. It will be analysed as a continuous measure.

8. Service use and costs will be assessed at 6 and 12 months using the modified Client Services receipt Inventory (CSRI) for people with intellectual disabilities adapted for the study (50). It will be completed with carers and used to assess costs related to service use in the last six months. This will be analysed as a continuous measure.

Outcomes in volunteers

1. Self-esteem will be measured using the 10 item Rosenberg self-esteem scale (51) at six months and 12 months after matching and will be analysed using a continuous measure.

2. Psychological wellbeing and quality of life will be measured using the Warwick- Edinburgh mental wellbeing scale (WEMWBS; 52) at six and 12 months. This measure has been developed to measure wellbeing in the general population and has been validated in different populations. It comprises 14 items, with scores ranging from 14-70 and has robust psychometric properties. This will be analysed as a continuous variable.

3. Loneliness will be measured using the UCLA loneliness scale at 6 and 12 months (53). This is a 20 item self-rated measure that is widely used and has good psychometric properties. This will be measured as a continuous variable.

4. Attitudes of volunteers will be assessed using the 67 item, Attitudes Towards Intellectual Disability Questionnaire (ATTID; 54) at 6 and 12 months, which covers cognitive, affective and behavioural components of attitudes. This will be analysed as a continuous variable.

8.3 SAMPLE SIZE AND RECRUITMENT

8.3.1 SAMPLE SIZE CALCULATION

We have selected a sample size of 50 participants with ID based on pragmatic reasons. We do not have any estimates of the number of people with ID who are eligible and are likely to consent to taking part in the trial. A sample size of 50 will allow us to estimate the recruitment rate of 80% from those who are eligible, with a 95% Confidence Intervals of 68.9% to 91.1%. We are assuming a high recruitment rate as access to the intervention will only be available through the trial.

As we are interested in examining the recruitment rate of participants with ID and volunteers, the number of matched pairs and drop-out rates, the feasibility study by Florides (38) provides useful information. According to this study, 24 volunteers were recruited (target was 20), but only 14 were matched and successfully initiated relationships with individuals with ID. This is a 58% recruitment to relationship success rate. This means that 40% of volunteers dropped out before the intervention was initiated. Applying this information to our study, we would need to recruit 42 volunteers to ensure that 25 can be matched to an individual with ID (assuming 40% of the volunteers will drop out before matching). A sample size of 42 volunteers would give a recruitment to relationship success rate of 60% with a 95% confidence interval (CI) of between 45.1% to 74.9%.

In the above study (38), following matching, 11 out of 15 relationships lasted for six months or more (27% drop out from the intervention). A sample size of 50 would allow us to estimate a 30% drop out rate for all participants in the trial with a 95% Confidence Interval of 16.2% to 43.9 %.

8.3.2 PLANNED RECRUITMENT RATE

The recruitment period is 6 months. There are two participating befriending services and each service will need to recruit 5-6 participants with intellectual disability per month.

9 TRIAL DESIGN

9.1 OVERALL DESIGN

This is a two arm, parallel group, researcher blind pilot randomised controlled trial with 1:1 allocation. Fifty participants with ID who are eligible for the study will be randomly allocated to either the intervention arm (one to one befriending by a volunteer plus treatment as usual) or the control arm (Treatment as Usual and booklet of resources). The duration of the intervention will be 6 months. Outcome assessments will be carried out at baseline, six months and 12 months post randomisation. The main outcomes of interest are feasibility outcomes (recruitment, drop out rate). The primary clinical outcome will be depression at 12 months in order to assess medium term benefits and possible negative effects of befriending.

An economic evaluation will be conducted. A process evaluation, based on mixed methods, will be carried out to examine the delivery and adherence to intervention, and stakeholder views on the acceptability of the intervention and barriers and facilitators that may affect the implementation of a full scale trial.

Blinding

The research assistant carrying out the outcome assessments in people with ID will be blind to the intervention group and the participants with ID will be reminded not to disclose details of their allocated group to the research assistant. It will not be possible to blind the outcome assessments carried out in volunteers as they will only be in the intervention group. In order to prevent unmasking, the research assistant will not be involved in any of the processes related to the intervention. The completeness of blinding will be assessed by asking the research assistant carrying out the outcome assessments in people with ID whether he/she is able to guess correctly which group each individual was assigned to. If the guesses are close to 50%, this would indicate that the study has been well blinded.

9.2 RECRUITMENT

Two befriending services for people with ID have agreed to participate in the study. One is based in Hackney, (London) and the other is in Suffolk. Participants with ID will be recruited from existing and new referrals to the befriending schemes participating in the study and will be referred in their usual way (e.g. from intellectual disability services, housing schemes, service user and carer organisations). We will also recruit directly from local community ID services.

Participants with intellectual disability will be initially approached by the volunteering coordinator at the befriending service or clinician at the community ID service, who will briefly discuss the study and provide an information sheet. If the individual is interested in the study and consents to his/her details being passed on to the research team, the research assistant will contact the individual and discuss the study further. If the individual meets the eligibility criteria, they will be asked to provide written consent.

The befriending services will advertise and recruit volunteers as they do already (e.g. through newspaper advertisements, befriending and job websites, social media and recruitment events at colleges and universities). Study posters will be used as part of the recruitment strategy.

Interested volunteers will be asked to complete an application form and will be invited to an informal interview to assess their suitability in terms of empathy, organisational skills, relationship building, communication skills and motivation for taking part in the scheme. A Disclosure and Barring Service (DBS) check will be completed to ensure that they have no criminal records and references will be obtained. Given that people with ID are a vulnerable group, volunteers with any previous offence, including minor offences, will not be included in the study. Successful candidates will be invited to take part in the study and will be given an information sheet and asked to sign a consent form.

10 SELECTION OF PARTICPANTS

10.1 INCLUSION CRITERIA

i. Individuals with ID will need to be:

1. Aged 18 or over
2. Have mild or moderate intellectual disability (ID) (IQ 35 to 69), which will be assessed using the Wechsler Abbreviated Scale of Intelligence (55)
3. A score of 5 or more on the Glasgow Depression Scale for People with learning Disabilities (GDS-LD (42). This score is below the threshold for a diagnosis of depression but will indicate the presence of depressive symptoms.
4. Should not be attending education/ day service for more than two days a week
5. Be able to provide informed consent.

ii. Volunteers will need to be:

1. Aged 18 or over
2. Agree to being available once a week for at least one hour over a period of six months.

10.2 EXCLUSION CRITERIA

i. Individuals with ID will be excluded if they have:
1. Severe ID (IQ less than 35 and/or are non-verbal or have very limited communication and comprehension and therefore would not be able to complete the questionnaires) or no ID (IQ above 70)
2. A score below 5 on the GDS-LD
3. Unable to communicate in English
4. Unable to provide consent.

ii. Volunteers will be excluded if they:
1. Have a criminal record (any documented offence) recorded on their DBS (see section on confidentiality (12.1) on how DBS checks will be stored).
2. Are unable to provide two references or have unsuitable references

11 STUDY PROCEDURES AND SCHEDULE OF ASSESSMENTS

11.1 PARTICIPANT IDENTIFICATION

Participants with intellectual disability will be identified by staff (e.g. volunteer coordinators) at the befriending services who will review or screen personal identifiable information of individuals who have been referred for befriending and are on the waiting list. They will then carry out the initial approach, which will involve a brief discussion of the study with the potential participant, and if they are interested in taking part, permission will be obtained to pass their contact details to the study Research Assistant who will then arrange to meet the individual to discuss the study further and confirm their eligibility. Participants undergoing eligibility will be identified by a screening identification number.

11.2 INFORMED CONSENT PROCEDURE

It is the responsibility of the Investigator, or a person delegated by the Investigator to obtain written informed consent from each participant prior to participation in the trial, following adequate explanation of the aims, methods, anticipated benefits and potential hazards of the study. The person taking consent will assess the capacity of each individual with ID to take part in the study. All staff taking consent will be GCP trained, suitably qualified and experienced, and have been delegated this duty by the CI on the delegation log.

“Adequate time” must be given for consideration by the patient before taking part. The PI must record when the patient information sheet (PIS) has been given to the participant. In the event of any conflict between the person with ID and their support network, the person WILL NOT enter the study.

The Investigator or designee will explain the participants are under no obligation to enter the trial and that they can withdraw at any time during the trial, without having to give a reason.

No research procedures will be conducted prior to taking consent from the participant. Consent will not denote enrolment into trial.

A copy of the signed Informed Consent form will be given to the participant. The original signed form will be retained at the study site and a copy placed in the case notes.

If new safety information results in significant changes in the risk/benefit assessment, the consent form will be reviewed and updated if necessary and participants will be re-consented as appropriate

11.3 SCREENING PERIOD

All the participants with intellectual disability who are interested in taking part will be assessed for the presence of a mild or moderate learning disability using the Wechsler Abbreviated Scale of Intelligence (WASI; 55) and will be screened for the presence of depressive symptoms using the Glasgow depression Scale in people with Learning Disability (GDS-LD; 44).

All participants who are volunteers and express an interest in taking part will have an informal interview, have DBS checks and References will be obtained to determine they are suitable. They will undergo training for the role once the DBS checks and references have been obtained. The baseline assessments will be carried out after training, prior to matching.

Screening does not constitute enrolment. If participants meet the eligibility criteria, consent to take part in the study will be obtained and they will complete the baseline assessments prior to randomisation.

a) The baseline assessment will occur within 2 weeks of the screening visit for participants with ID. For volunteers the baseline assessment will take place within 8 weeks after the screening (+/-2 weeks).
b) During the intervention, visits will occur +/- 7 days of the scheduled date
c) The follow up assessments will occur at 26 weeks and 52 weeks (+/- 14 days) after randomisation
d) Randomisation will be carried out following confirmation of eligibility at the baseline visit.

11.4 RANDOMISATION PROCEDURES

Participant randomisation will be undertaken by site staff logging into a web based system called Sealed Envelope that is centrally built and managed by Priment Clinical Trials Unit.

Following confirmation of eligibility, participant consent, and completion of the baseline measures, the randomisation procedure described below will be carried out.

After completion of baseline measures, patients will be randomised into the study by an admin research assistant who is not involved in the study. The research assistant will enter the patient's screening, baseline and eligibility details into the web based randomisation system which is hosted on a secure server by Sealed Envelope. This system will randomly allocate the participant to either the intervention or control arm and the participant will be given a study Identification number. The research assistant will inform the befriending service and participants with ID of their allocation and will inform an unblinded member of the research team.

Randomisation will be blocked using randomly varying block sizes, stratified by centre. The allocation schedule will be concealed through the use of this central web-based randomisation service. The randomisation protocol will be created by the trial statistician and the set up of the service will be overseen by the Priment Clinical Trials Unit, in accordance with its Standard Operating Procedures.

In order to ensure that randomization is concealed, the befriending service, the participants at the time of enrollment and the research team will have no knowledge of the allocation prior to the start of the intervention. It will not be possible to blind the participants to the allocation group. However, the research assistant carrying out the outcome assessments will be blind to the allocation group. At the end of the study we will assess researcher blindness by asking them to guess the allocated group.
Participants are considered to be enrolled into the trial following: consent, pre-treatment assessments (see section 8.1), confirmation of eligibility, completion of the randomisation process, allocation of the participant trial number and intervention by the central coordinating team.

11.5 BASELINE ASSESSMENTS

i. Assessments for participants with ID

1. Depressive symptoms will be measured using the GDS-LD (42)

2. Self esteem will be measured using the adapted Rosenberg self-esteem scale for people with intellectual disabilities (43).

3. Quality of life will be assessed using the Maslow Assessment of Needs Scale-Learning Disability (MANS-LD; (44)) and the adapted World Health Organisation Quality of Life questionnaire (WHO-QOL-8; (45))

4. Loneliness and social satisfaction will be measured using the Modified Worker Loneliness Questionnaire (MWLQ (46)

5. Social support will be measured using the Social Support Self Report for intellectually disabled adults (SSSR) (47)

6. Social participation will be measured using the Guernsey Community Participation and Leisure Assessment (48).

7. Health related quality of life will be measured using the EuroQol-Youth (EQ-5D-Y) (49).

8. Service use and costs will be assessed using the modified CSRI for people with intellectual disabilities adapted for the study (50).

9. Socio-demographic questionnaire (comprising questions on age, sex, ethnicity, living circumstances and pre-existing medical or psychiatric conditions)

10. Adverse Events review and concomitant medication review

11. Confirmation of Eligibility

12. Randomisation (see section 11.4)

ii. Assessments in volunteers

1. Self-esteem will be measured using the 10 item Rosenberg self-esteem scale (51)

2. Psychological wellbeing and quality of life will be measured using the Warwick- Edinburgh mental wellbeing scale (WEMWBS; 52).

3. Loneliness will be measured using the UCLA loneliness scale (53).

4. Attitudes of volunteers will be assessed using the 67 item, Attitudes Towards Intellectual Disability Questionnaire (ATTID; 54)

5. Adverse Events review

6. Socio-demographic questionnaire comprising questions on age, sex, ethnicity and employment.

11.6 TREATMENT PROCEDURES

i. Befriending intervention

This befriending intervention has been adapted from other studies of befriending (38, 56). The purpose of the befriending relationship will be to provide friendship and emotional support to the person with ID, and to provide support to the individual to access activities in the community that they may be unable to do themselves. The volunteer (befriender) and person with ID will be expected to meet at least once a week for one hour, over a six month period. The volunteer will provide face to face contact and will arrange to meet the person at their home, or another place.

The volunteer and person with ID will receive a booklet about local activities and amenities, which they will use to plan activities. The volunteer will support the individual with ID to access activities in the community, depending on the individual's needs or requests. The emphasis will be on helping the individual to make choices about the activities that they wish to do, and not simply doing activities suggested by the volunteer. The remit of the volunteer's role could include spending time together in a cafe, but the volunteer would not be expected to carry out personal care, administer medication or take the individual to medical appointments. Contacts by phone/social media can take place in addition to the face to face sessions. If the participant does not wish to go out, the pair could spend some sessions in the person's home but this should not exceed 50% of the total number of sessions. Sessions may take place during evenings/weekends depending on the pair's availability. They will be requested to keep a record of their activities in a structured log that will be provided (whether they attended each session, reasons for cancellation, what they did in each session and duration of activity), and will include a record of other types of contact. Volunteers will be reimbursed expenses incurred during sessions (e.g. travel fares, price of tickets).

ii. Matching of individuals with ID to volunteers and monitoring of the relationship

Individuals with ID and volunteers will complete a form about their hobbies, interests and availability. Individuals with ID will provide information about what activities they would like support to attend or what they would like to obtain from the befriending relationship (e.g. emotional support). Based on this information, participants with ID will be matched to a volunteer that can accommodate the person's interests. The volunteering coordinator will then arrange a face to face meeting at week 1 (+/- 7days) where the pair will be introduced to each other. Following this, both parties can decide whether to continue. If they agree, then the pair will continue to meet on their own; if they decide that the pairing is unsuitable, they will be re-matched. Once the pair has met on their own on at least one occasion, further re-matching will not be offered even if the volunteer drops out subsequently. If the volunteer fails to turn up to their first session, then the individual will be matched to another volunteer, or if the individual with ID does not attend, then the volunteer will be matched to another individual. The pair will be asked to agree/sign a contract of conduct, which describes the boundaries of the relationship, how both parties should be treated, and circumstances that could lead to the termination of the relationship (e.g. abuse towards the volunteer or safeguarding issues).The volunteering coordinator will arrange a face to face meeting after six weeks (+/- 7days) to monitor the progress of the relationship. The pair will then be contacted by phone every four weeks by the volunteer coordinator, who will attempt to resolve any disputes or difficulties that may be encountered in the relationship. If the individual with ID has a carer, he or she will also be contacted every four weeks to obtain feedback about the relationship and to identify any potential concerns. A further meeting will be held at the end of the six months (week 24 +/- 7days) to obtain general feedback about the befriending intervention, to discuss ending the relationship and to support the individual with ID with coming to terms with the ending. It is expected that the pair will meet for a minimum of six months but there is no limit on how long the relationship may last. The pair may continue their relationship if they wish after the six month period. Both befriending services currently support short and long term relationships.

iii. Training and supervision of volunteers

The volunteers will attend a comprehensive training course provided by the befriending service. This will be given as face to face or as e-learning. The training will include the following: 1. introductory session where volunteers will be introduced to the scheme and its core values, the benefits of befriending and issues related to confidentiality and lone working; 2.Safeguarding training (e-learning) providing information on identifying the signs of abuse and how to respond appropriately; 3. Making Every Contact Count Training (1 and half hours), which offers advice about how to plan meetings effectively; 4. Disability Awareness training (half day), aimed at developing a better understanding of ID, the difficulties faced by individuals (including stigma and discrimination) and how to communicate and support individuals with ID; 5. Professional boundaries (2 hours) which covers dealing with sensitive issues, ending relationships and expectations of the role of the volunteer; 6. and autism and anxiety training (e-learning), covering the core features of these conditions.

Volunteers will have access to group or individual supervision that will be provided once a month by the befriending scheme, which may be face to face or over the phone to accommodate those

working full time. The supervision sessions will address issues that may have arisen from the relationship, for example, concerns about the befriendee's mental health or behaviour or advice about how the befriending sessions can be used to support the befriendee's needs. Volunteers who are providing support at weekends or evenings will be asked to follow the lone working policy. They will be asked to follow guidelines about whom they should contact and what they should do in the event of an emergency (e.g. individual with ID expressing thoughts of self harm or suicide).

Control Arm

Participants in the control arm will also receive a booklet about local resources, amenities and groups that they can contact. They will meet with a research assistant once who will go through the booklet with them (and their carer, if present).

Both the control and intervention arms will also have access to "Usual Care". This will include access to multidisciplinary input from community intellectual disability services such as contact with psychiatrists, psychologists, nurses and social workers. Participants can continue to take their medication, including antidepressant medication and will also be able to access other community based services such as contact with their General Practitioner. They will have access to hospital based health services, and day services (day centres, social clubs and education).

Incentives

The participants with ID and volunteers taking part in the study will each receive £10 for completing assessments at baseline and each follow up assessment (£30 in total each) in order to thank them for their time.

11.7 SUBSEQUENT ASSESSMENTS

The following measures will be administered at 6 months (week 26 +/-14 days) and 12 months (week 52 +/- 14 days) post randomisation at the participants' homes or befriending service. See sections 8.1 and 8.2 on outcome measures for further information about the measures.

i. Assessments for participants with ID

1. Depressive symptoms will be measured using the GDS-LD (42),

2. Self esteem will be measured using the adapted Rosenberg self-esteem scale for people with intellectual disabilities (43).

3. Quality of life will be assessed using the Maslow Assessment of Needs Scale-Learning Disability (MANS-LD; (44)) and the adapted World Health Organisation Quality of Life questionnaire (WHO-QOL-8; (45).

4. Loneliness and social satisfaction will be measured using the Modified Worker Loneliness Questionnaire (MWLQ (46),

5. Social support will be measured using the Social Support Self Report for intellectually disabled adults (SSSR)(47)

6. Social participation will be measured using the Guernsey Community Participation and Leisure Assessment (GCP-LA) (48)).

7. Health related quality of life will be measured using the EuroQol-Youth (EQ-5D-Y), (49).

8. Service use and costs will be assessed using the modified Client Services receipt Inventory for people with intellectual disabilities adapted for the study (50).

9. Review adverse events and concomitant medication: obtain description/accounts of concerns raised by participant or carers, including discussions with volunteer coordinator. Record information on hospital admissions, worsening mental health/relapse and emotional distress (e.g. due to termination of befriending relationship), any medications that have been prescribed.

ii. Assessments in volunteers

1. Self-esteem will be measured using the 10 item Rosenberg self-esteem scale (51)

2. Psychological wellbeing and quality of life will be measured using the Warwick- Edinburgh mental wellbeing scale (WEMWBS; 52)

3. Loneliness will be measured using the UCLA loneliness scale (53).

4. Attitudes of volunteers will be assessed using the 67 item, Attitudes Towards Intellectual Disability Questionnaire (ATTID; 54)

5. Review adverse events: obtain description of accounts/concerns raised by volunteers.

A schedule of all trial assessments and procedures is set-out in section 11.8

Process evaluation and user experience qualitative evaluation

The process evaluation will be based on MRC guidance (57). The aim of the process evaluation will be to examine whether the different components of the intervention (recruitment, training and supervision) were consistently followed by the participating befriending services; the extent to which the delivery of one to one befriending by volunteers is delivered as planned; the extent to which the intervention would need to be modified prior to a full trial in order to make it more acceptable to participants or volunteers; understanding the perceived value, benefits and harm or unintended consequences of the intervention so that these are fully measured in the full trial and

developing an understanding of the likely mechanisms of action of the intervention. In order to carry out the process evaluation, a mixed methods approach employing qualitative and quantitative approaches will be used.

Qualitative study

The aim of the qualitative study is to explore the views of stakeholders: individuals with ID, volunteers, carers of people with ID and staff from the befriending organisations taking part in the study. We will interview 16 participants with ID after they have completed their 52 week follow up (8 per site including two who dropped out if the intervention). We will carry out two focus groups with 5-8 volunteers at each site, two focus groups with staff from each befriending service, and two focus groups with 5-8 carers at each site. We will use purposive sampling in order to include people with a range of demographic characteristics, and both service users and volunteers for whom the befriending relationship broke down, as well as people who completed the intervention. Topic guides for each participant group will be developed in consultation with the study advisory group and the study team. All respondents will be asked about what aspects of the intervention were successful and perceived to be helpful, what aspects require improvement or modification, views about recruitment and trial procedures, what the perceived barriers or facilitators are to delivering the intervention, and any suggested improvements to the intervention. Service users will be asked about whether there were any perceived benefits of the intervention; Carers will be asked about the perceived impact of the intervention for the participant, and for them, and if/how any benefits were achieved. Volunteers will be asked about their views on whether they thought the training and supervision offered was sufficient. Staff from the befriending services will be asked about whether they encountered challenges in adhering to the trial protocol. The interviews will be audio-taped and transcribed. Transcripts will be analysed using thematic analysis supported by computer software (NVivo 9). The analytic strategy will seek to answer our initial research questions with a particular focus on identifying barriers and facilitators to implementing the intervention successfully, its benefits to participants and mechanisms of effect. Analysis will also allow consideration of themes that arise more inductively from the data. Validity will be enhanced by a collaborative analytic strategy involving members of the research team and representatives of the advisory group.

Quantitative process

We will collect data on the uptake of supervision and the frequency of monitoring checks and visits from routine records provided by the volunteering coordinator at each site. We will use data from the structured session logs provided by volunteers for each 1:1 meeting with a participant for two purposes:

i) We will check whether key elements of the befriending intervention were delivered as intended: a) how many meetings each participant attended, and how many participants met the minimum set threshold of 10 sessions during the 6-month intervention period; and b) for how many participants the minimum threshold of at least 50% of meetings being outside the participant's home was achieved.

ii) We will describe the location (at home or in the community) and content of the befriending meetings. We will describe the range of activities undertaken. In collaboration with participating services and the advisory group, we will develop a framework to categorise different types of activity

during befriending meetings. This will enable us to distinguish and quantify different types of befriending support (e.g. 1:1 conversation; 1:1 practical support (e.g. going shopping); 1:1 social activity (e.g. going swimming, or to a movie together; social activity involving others (e.g. going to a group or community social activity).

We will develop and test procedures for collecting quantitative process data which, in a future larger trial, could be used to explore the relationships between process variables and outcomes. In our trial, findings from the qualitative and quantitative process evaluation will inform any necessary refinements to the study intervention manual or training and supervision arrangements, and identify the most appropriate outcome measures and measures of mechanisms for use in a future definitive trial.

11.8 FLOWCHART OF STUDY ASSESSMENTS

Table 1: Schedule of assessments/ procedures for participants with Intellectual Disability

	Screening	Baseline	Treatment Phase			Final visit/ FU	Qualitative study
Visit #	1	2	3	4	5	6	7
Week/month	- Week – 2	0	Week 1 (+/- 7 days	Week 6 (+/- 7 days	Week 26 (end of interventi on) +/- 7 days	Week 52 (+/- 7 days)	52 weeks to 60 weeks
Informed Consent	X						
Socio-demographic questionnaire		X					
Eligibility determination	X	X					
WASI	X						
GDS-LD	X	X			X	X	
Rosenberg self esteem questionnaire		X			X	X	
MANS-LD		X			X	X	
WHO-QOL-8		X			X	X	
MWLQ		X			X	X	

SSSR		X			X	X	
GCPLA		X			X	X	
EQ-5D-Y		X			X	X	
CSRI		X			X	X	
Semi-structured interview							X
Randomisation		X					
Introduction to volunteer			X				
Review by Volunteer coordinator				X	X		
Adverse Events review		X			X	X	
Concomitant Medication review		X			X	X	

Table 2: Schedule of assessments/procedures for volunteers

	Screening	Baseline	Intervention						F/U	Qualitative study
Visit #	1	2	3	4	5	6	7	8	9	10
Week	week – 8 (+/- 14 days)	0	1 (+/- 14 days	6 (+/- 7 days)	12 (+/- 7 days)	16 (+/- 7 days)	20 (+/- 7 days)	24 (+/- 7 days)	52 (+/- 7 days)	52-55 (+/- 7 days)
Informed Consent	X									
Informal interview	X									
DBS checks	X				X					
References	X									
Training	X									
Socio-demographic questionnaire		X								
Rosenberg Self Esteem Scale		X						X	X	
WEMWBS		X						X	X	
UCLA		X						X	X	

ATTID		X						X	X	
Introduction to person with ID			X							
Review by Volunteer Coordinator				X				X		
Supervision				X	X	X	X	X		
Focus group										X
Adverse Events review		X						X	X	

11.9 METHODS

11.9.1 LABORATORY PROCEDURES

N/A

11.10 DEFINITION OF END OF TRIAL

The expected duration of the trial is 18 months from recruitment of the first participant.
The end of trial is the date of the last follow up/home visit of the last participant.

11.11 DISCONTINUATION/WITHDRAWAL OF PARTICIPANTS AND 'STOPPING RULES'

A participant (Individual with intellectual disability or volunteer) may be withdrawn from trial whenever continued participation is no longer in the participant's best interests, but the reasons for doing so must be recorded. Reasons for discontinuing the trial may include:

- Worsening depressive symptoms or other mental illness
- Intercurrent physical illness
- Participants withdrawing consent
- Persistent non-compliance with protocol requirements.
- Concerns about safeguarding (abuse or exploitation of participant with ID)
- Concerns about risk to volunteer (e.g. verbal or physical aggression)

The decision to withdraw a participant from treatment will be recorded in the CRF and medical notes. If a participant explicitly states they do not wish to contribute further data to the trial their decision must be respected and recorded in the CRF and medical notes.

Volunteers who do drop out before being matched to an individual with intellectual disability will be replaced by another volunteer.

A decision to stop the trial prematurely will be made in conjunction with the Trial Steering Committee and study Sponsor if there are concerns about the number and nature of adverse events (e.g. suicide) or due to poor recruitment to the trial.

11.12 CONCOMITANT MEDICATION

Participants are permitted to take medication that they usually take as part of routine care. Medication will not be administered by the study team.

11.13 POST-TRIAL ARRANGEMENTS

If participants with intellectual disability and their volunteers wish to continue their befriending relationship after the 6 month intervention period, they may do so. Their relationship will continue to be monitored by the local befriending service.

12 DATA MANAGEMENT

All aspects of data management of the study will comply with the General Data Protection Regulations together with the new Data Protection Act 2018 (DPA 2018), Priment SOPs and GCP.

12.1 CONFIDENTIALITY

The Case Report Forms (CRFs) will not bear the participant's name. The participant's initials, date of birth and trial identification number will be used for identification. Any personal data collected will be managed according to Priment SOP Managing Personal Data.

Copies of DBS Checks will be stored securely in a locked filling cabinet within a locked room (separate from the study database) and will only be kept until the follow up assessments are completed. They will then be disposed of securely.

12.2 DATA COLLECTION TOOLS

The data collection tools will be created according to Priment SOP Development, Review and Approval of Case Report Forms.

12.3 TRIAL DATABASE

Data will be collected using paper forms and then the CRFs will be entered into a web-based clinical data management system, Red Pill, provided by Sealed Envelope through Priment. Sealed Envelope

has been assessed by Priment to ensure that adequate processes are in place and are being followed for quality management, software development and security. Database services and support will be delivered through a contract signed by Sealed Envelope and UCL.

Priment SOPs Validating Sealed Envelope Systems and Change Control for Sealed Envelope Systems will be followed to set up and manage changes to the trial database.

At the end of the trial, prior to analysis, Priment SOP Database Lock, Unlock and Closure will be followed.

12.4 DATA COLLECTION AND HANDLING

All data will be collected and handled in accordance with Priment SOP Data Handling.

It will be the responsibility of the investigator to ensure the accuracy of all data entered in the CRFs. The delegation log will identify all those personnel with responsibilities for data collection and handling, including those who have access to the trial database.

12.5 DATA OWNERSHIP

At the end of the trial, the data belongs to UCL. UCL will be the Data controller.

13 RECORD KEEPING AND ARCHIVING

At the end of the trial, all essential documentation will be archived securely by the CI for a minimum of 20 years from the declaration of end of trial.

Essential documents are those which enable both the conduct of the trial and the quality of the data produced to be evaluated and show whether the site complied with all applicable regulatory requirements. The sponsor will notify sites when trial documentation can be archived. All archived documents must continue to be available for inspection by appropriate authorities upon request.

The trial database will be retained for 10 years after the end of the study.

14 STATISTICAL CONSIDERATIONS

Professor Rumana Omar, the senior trial statistician and Rebecca Jones, the trial statistician will be responsible for all statistical aspects of the trial from design through to analysis and dissemination.

14.1 STATISTICAL ANALYSES

14.1.1 SUMMARY OF BASELINE DATA AND FLOW OF PARTICIPANTS

The characteristics of participants by trial arm will be summarised using mean (SD) or medians (IQ range) for continuous variables and counts (percentage) for categorical variables.

The flow of participants in the trial will be recorded on a consort flow diagram (http://www.consort-statement.org/).

14.1.2 PRIMARY OUTCOME ANALYSIS

The primary outcome analysis will involve analysing the feasibility outcomes.

Feasibility outcomes such as the number of participants who were screened and eligible, recruitment rate of participants with ID and volunteers, and the number of successful matched relationships will be reported. The number (proportion) of drop outs in the intervention and control arm will also be reported, including reasons why. This information will be presented in a Consort diagram describing the flow of participants through the study.

14.1.3 SECONDARY OUTCOME ANALYSIS

Appropriate regression models depending on the type of outcome, adjusted for baseline values will be used to estimate the intervention effect on health outcomes. The results will be presented as estimates with 95% Confidence intervals. All analyses will be carried out as allocated and will be exploratory due to the small sample size.

14.1.4 SENSITIVITY AND OTHER PLANNED ANALYSES

- Not planned

14.2 INTERIM ANALYSIS

- Not planned

14.3 OTHER STATISTICAL CONSIDERATIONS

Deviations from the original statistical plan will be justified in the final report.

15 QUALITATIVE METHODS

Transcripts from the focus groups and interviews will be analysed using thematic analysis supported by computer software (NVivo 9). The analytic strategy will focus on identifying barriers and facilitators to implementing the intervention successfully, its benefits to participants and mechanisms of effect. Analysis will also allow consideration of themes that arise more inductively from the data. Validity will be enhanced by a collaborative analytic strategy involving members of the research team and representatives of the advisory group.

16 ECONOMIC EVALUATION

Economic evaluations informs planning of future economic analyses, sources of data required and how best to collect these data. We will assess the feasibility of calculating the quality-adjusted life years (QALYs) using the EuroQol-Youth (EQ-5D-Y) (49).

We will calculate the costs of delivering the intervention (recruitment, training, supervision and expenses) Data on the costs will be obtained from each participating befriending service.
Information on resource use by participants with ID in both arms of the trial will be collected using the Client Service Receipt Inventory (50), which has been adapted for people with ID. Data will be obtained at baseline and at each follow up points. NHS and social care resource use data will include contacts with health professionals such as psychiatrists, psychologists community nurses and social workers within community learning disability teams, consultations with GPs, contacts with psychological services such as IAPT (Improving Access to Psychological Services), contacts with hospital based services including Accident & Emergency department and admissions to general and psychiatric hospital, and use of day care services such as day centres and respite. Information on costs of investigations and treatments (e.g. antidepressants, other psychotropic medication and over the counter medication) will also be collected.

Resource use will be costed using published sources, PSSRU (58) and NHS reference costs (59).
Costs will be reported from health and social care perspective.

The total costs will be compared in each group using a bootstrapped regression model as costs are likely to be positively skewed.

We will provide an initial estimate of the incremental mean cost per QALY gained in the intervention compared to control groups. The mean QALY per participant with ID will be calculated as the area under the curve for the duration of the trial, adjusting for baseline values. Confidence intervals will be constructed using non-parametric bootstrapping with replacement.

17 NAME OF COMMITTEES INVOLVED IN TRIAL

There will be a patient and public (PPI) advisory group, Trial Management Group and Trial Steering Group who will oversee the trial.

The TMG will include the Chief Investigator, Priment Clinical Trials Unit and trial staff. The TMG will be responsible for overseeing the trial. The group will meet regularly (every three months, four times a year) and will send updates to PIs .

The TMG will review recruitment figures, SAEs and substantial amendments to the protocol prior to submission to the REC. All PIs will be kept informed of substantial amendments through their nominated responsible individuals.

The Priment Clinical Trials Unit will ensure that the trial processes and procedures meet the requirements of Good Clinical Practice (GCP) and will complete quality assurance checks.
There will be a Trial Steering Committee (TSC). The role of the TSC is to provide overall supervision of the trial. The TSC will recommend any appropriate amendments/actions for the trial as necessary. The TSC acts on behalf of the funder(s) and Sponsor. The Trial Steering Committee will comprise an independent chair, an independent statistician, independent clinician with expertise in ID, the chief investigator, and at least one family carer of an adult with ID.

There will also be a PPI advisory group. This group will comprise Carers and current volunteers and befriendees with ID (six in total) from the two participating befriending organisations. They will provide advice about the study information sheets, consent forms, topic guides for the qualitative interviews, results of the study findings and the final study report. Two members will be invited to be part of the Trial Management Group (TMG) and another two will be involved in carrying out the qualitative interviews and focus groups as part of the process evaluation, and will receive training and support for this role. We will also invite one carer and individual with ID to attend and provide feedback about the study at the public engagement seminar at the end of the study.

There will not be an Independent Data Monitoring Committee as this is a small pilot study.

18 RECORDING AND REPORTING OF ADVERSE EVENTS AND REACTIONS

18.1 DEFINITIONS

Term	Definition
Serious Adverse Event (SAE)	Any untoward occurrence that: • results in death, • is life-threatening, • requires hospitalisation or prolongation of existing hospitalisation, • results in persistent or significant disability or incapacity, or • consists of a congenital anomaly or birth defect • is otherwise considered medically significant by the investigator
Suspected Unexpected Serious Adverse Reaction (SUSAR)	Any SAE that is deemed to be • Related to the trial intervention AND • Unexpected (not listed in the protocol as an expected side effect of the intervention)

18.2 EXPECTED SIDE EFFECTS

There may be some anxiety associated with the intervention, particularly at the beginning, when the volunteer and individual with ID begin to develop their relationship and establish a rapport. The following side effects are effects of the intervention that are known or expected and will be considered when assessing the expectedness of an event that is reported: There may be an increase in depressive symptoms/ emotional distress following the ending of the befriending relationship.

18.3 RECORDING ADVERSE EVENTS

Information about adverse events will be collected by the research assistant at each follow up assessment using open- ended questions. Adverse events may also be reported directly to the Chief Investigator by the befriending organisations taking part in the study. All adverse events will be recorded in the medical records, CRFs or other designated place following consent. Serious adverse events will also be recorded in the SAE log. All adverse events will be recorded with clinical symptoms and accompanied with a simple, brief description of the event, including dates as appropriate. All adverse events will be recorded until the end of the trial.

18.4 ASSESMENTS OF ADVERSE EVENTS

Each serious adverse event will be assessed to determine if the event is related to the intervention and if the event is expected.

A. RELATED EVENTS

The assessment of the relationship between adverse events and the administration of the intervention is a decision based on all available information at the time of the completion of the case report form. If the event is a result of the administration of any of the research procedures then it will be classed as related.

B. EXPECTED EVENTS

If the event has been listed in the protocol (section 18.2) as an expected side effect of the intervention then the event will be classed as expected. If the event is not listed then it will be classed as unexpected.

18.5 PROCEDURES FOR REPORTING SERIOUS ADVERSE EVENTS

Any serious adverse events which are classed as related and unexpected will be reported to the ethics committee that approved the trial and to Priment.

The reporting of adverse events to the ethics committee and sponsor will be completed according to Priment non-CTIMP safety management SOP or to any other specific requirements if the Sponsor of the trial is not UCL.

The Chief Investigator (or their delegate) is responsible for reporting SUSARs to the ethics committee that approved the study within 15 calendar days of becoming aware of the event.

The CI will review reports from the PI and will complete the sponsor's SAE form and the form will be emailed to the Sponsor within 5 working days of becoming aware of the event. The Chief Investigator will respond to any SAE queries raised by the sponsor as soon as possible. Safety information will be disseminated via email to each of the PIs/ sites.

18.6 THE TYPE AND DURATION OF THE FOLLOW-UP OF PARTICIPANTS AFTER ADVERSE EVENTS

Follow-up should continue after completion of protocol treatment for as long as necessary until clinical recovery is complete and laboratory results have returned to normal or baseline values, or until the event has stabilised.

18.7 ANNUAL PROGRESS REPORTS

An annual progress report (APR) will be submitted to the REC within 30 days of the anniversary date on which the favourable opinion was given, and annually until the trial is declared ended.

The Chief Investigator will prepare the APR.

18.8 REPORTING URGENT SAFETY MEASURES

If any urgent safety measures are taken, the PI/Sponsor shall immediately and in any event no later than 3 days from the date the measures are taken, give written notice to REC of the measures taken and the circumstances giving rise to those measures.

18.9 NOTIFICATION OF SERIOUS BREACHES TO GCP AND/OR THE PROTOCOL

A "serious breach" is a breach which is likely to affect to a significant degree –

(a) The safety or physical or mental integrity of the participants of the trial; or

(b) The scientific value of the trial.

The sponsor of a clinical trial shall notify the licensing authority in writing of any serious breach of –

(a) the conditions and principles of GCP in connection with that trial; or (b) the protocol relating to that trial, as amended from time to time, within 7 days of becoming aware of that breach.

The sponsor will be notified immediately of any case where the above definition applies during the trial conduct phase. The sponsor's SOP on 'serious breaches' will be followed.

19 MONITORING AND INSPECTION

A monitoring plan will be established for the trial based on the risk assessment. The trial will be monitored with the agreed plan.

The investigator(s)/ institution(s) will permit trial-related monitoring, audits, REC review, and regulatory inspection(s), providing direct access to source data/documents. Trial participants are informed of this during the informed consent discussion. Participants will consent to provide access to their medical notes.

20 ETHICS AND REGULATORY REQUIREMENTS

The Sponsor will ensure that the trial protocol, patient information sheet, consent form, Assent forms, GP letter and submitted supporting documents have been approved by the appropriate ethics committee, prior to any participant recruitment. The protocol and all agreed substantial protocol amendments, will be documented and submitted for ethical prior to implementation.

Before sites can enrol participants into the trial, the Chief Investigator/ Principal Investigator or designee must apply for permission from their site organisations and be granted written permission. It is the responsibility of the Chief Investigator/ Principal Investigator or designee at each site to ensure that all subsequent amendments gain the necessary approval. This does not affect the individual clinician's responsibility to take immediate action if thought necessary to protect the health and interest of individual participants (see section for reporting urgent safety measures).

Within 90 days after the end of the trial, the CI/Sponsor will ensure that the main REC is notified that the trial has finished. If the trial is terminated prematurely, those reports will be made within 15 days after the end of the trial.

The CI will supply the Sponsor with a summary report of the clinical trial, which will then be submitted to the main REC within 1 year after the end of the trial.

Only participants who are able to consent to taking part in the study, will be included. Accessible information sheets will be developed with input from the PPI advisory group set up for the study in order to ensure that information about the study is communicated clearly.

20.1 PUBLIC AND PATIENT INVOLVEMENT

The research proposal has been developed in consultation with three befriending organisations, whom have provided insights into the nature of the befriending intervention and the challenges posed by recruitment, successful matching of volunteers to individuals and the monitoring of the relationship. In addition, advice was obtained from a consultation group that was held at the Suffolk befriending scheme with three current volunteers, two befriendees with ID and two volunteering coordinators

Patients/public will also be involved in the management, undertaking and dissemination of research. There will be a PPI advisory group that will meet every six months. This group will comprise Carers and current volunteers and befriendees with ID (six in total) from the two participating befriending organisations. They will provide advice about the study information sheets, consent forms, topic guides for the qualitative interviews, results of the study findings and the final study report. Two members will be invited to be part of the Trial Management Group (TMG) and another two will be involved in carrying out the qualitative interviews and focus groups as part of the process evaluation, and will receive training and support for this role. We will also invite one carer and individual with ID to attend and provide feedback about the study at the public engagement seminar at the end of the study.

Members of the PPI group will receive payment for their time, which will include payment for preparation as well as attendance at meetings. Individuals attending the Trial Management Group meetings and Trial Steering Committee will be reimbursed travel costs as well as payment for meeting preparation and attendance.

21 FINANCE

The study has received funding from the Public Health Research (PHR) funding stream of the NIHR (study reference 16/122/57).

There are no financial conflicts of interests by the PI, research/trial staff or befriending services taking part in the study.

22 INSURANCE

University College London holds insurance against claims from participants for injury caused by their participation in the clinical trial. Participants may be able to claim compensation if they can prove that UCL has been negligent. University College London does not accept liability for any breach in the NHS organisation or an organisation contracted to the NHS's duty of care, or any negligence on the part of NHS organisation employees. This applies whether the NHS organisation is an NHS Trust or otherwise.

Participants may also be able to claim compensation for injury caused by participation in this clinical trial without the need to prove negligence on the part of University College London or another party. Participants who sustain injury and wish to make a claim for compensation should do so in writing in

the first instance to the Chief Investigator, who will pass the claim to the Sponsor's Insurers, via the Sponsor's office.

23 PUBLICATION POLICY

All proposed publications will be discussed with Sponsor prior to publishing other than those presented at scientific forums/meetings. Please refer to UCL publication policy.

24 STATEMENT OF COMPLIANCE

The trial will be conducted in compliance with the approved protocol, the UK Regulations, EU GCP, General Data protection regulations and Data protection Act 2018 and other relevant applicable regulatory requirement(s).

25 INTELLECTUAL PROPERTY

All background intellectual property rights (including licences) and know-how used in connection with the study shall remain the property of the party introducing the same and the exercise of such rights for purposes of the study shall not infringe any third party's rights.

All intellectual property rights and know-how in the protocol and in the results arising directly from the study, but excluding all improvements thereto or clinical procedures developed or used by each participating site, shall belong to UCL. Each participating site agrees that by giving approval to conduct the study at its respective site, it is also agreeing to effectively assign all such intellectual property rights ("IPR") to UCL and to disclose all such know-how to UCL.

Each participating site agrees to, at the request and expense of UCL execute all such documents and do all acts necessary to fully vest the IPR in UCL.

Nothing in this section shall be construed so as to prevent or hinder the participating site from using know-how gained during the performance of the study in the furtherance of its normal activities of providing or commissioning clinical services, teaching and research to the extent that such use does not result in the disclosure or misuse of confidential information or the infringement of an intellectual property right of UCL. This does not permit the disclosure of any of the results of the study, all of which remain confidential.

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