The BRIDGE project: A feasibility randomised controlled trial of brief, intensive assessment and integrated formulation for young people (age 14-24) early in the course of borderline personality disorder

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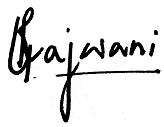
SIGNATURE PAGE

Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement.

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 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.

Name	**Role**	**Signature**	**Date**
Dr Ruchika Gajwani	Chief Investigator		**26/04/2023**
Name	**Role:**	**Signature**	**Date**
Ms Alison Hamilton	NHS R&D Sponsor representative		

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Glossary of abbreviations

ACES	Adverse Childhood Experiences Scale
ADHD	Attention Deficit Hyperactivity Disorder
AE	Adverse Event
ANCOVA	Analysis of Covariants
APR	Annual Progress Report
ASRS	Adult ADHD Self-Reporting Scale
ASSERT	Autism Symptoms SElf-reporT for adolescents and adults
BIS	Brief Impulsiveness Scale
BRIDGE	Brief Intensive Assessment and Integrated Formulation
BPD	Borderline Personality Disorder
BSL-23	Borderline Symptoms List -23
CAMHS	Children and Adolescent Mental Health Services
CAT	Cognitive Analytic Therapy
CI	Chief Investigator
CI	Confidence Intervals
CNORIS	Clinical Negligence and Other Risks Indemnity Scheme
CRN	Clinical Research Nurse
d-RCT	Definitive Randomised Controlled Trial
DSM-V	Diagnostic Statistic Manual-V
f-RCT	Feasibility Randomised Controlled Trial
GCP	Good Clinical Practice
GG&C	Greater Glasgow & Clyde
GP	General Practitioner
ICECAP-A	ICEpop CAPability measure for Adults
ISMS	Intensive Support and Monitoring Service
N	Number of Participants

NHS GG&C	National Health Service Greater Glasgow & Clyde
NHS R&D	National Health Service Research and Development
NRES	National Research Ethics Service
PHQ-9	Patient Health Questionnaire-9
PI	Principle Investigator
PIS	Patient Information Sheet
PPIe groups	Patient and Public Involvement and engagement
RCT	Randomised Controlled Trial
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SAU	Service as Usual
SDS	Sheehan's Disability Scale
SSC	Study Steering Group
YPAG	Young Person's Advisory Group

1 Synopsis

Short title	The BRIDGE project: A feasibility randomised controlled trial of brief, intensive assessment and integrated formulation for young people (age 14-24) early in the course of borderline personality disorder
Study Centre	University of Glasgow & NHS GG&C
Duration of Study	36 months
Objectives	To assess the feasibility of conducting a randomised controlled trial (f-RCT) of a BRIDGE, a brief intervention programme for young people (age 14-24) with early BPD (sub-threshold or threshold) in the general population of Glasgow, Scotland.
Primary Objectives	Are young people with early BPD willing to be randomised to BRIDGE (AND service as usual) or service as usual (ALONE) and can sufficient numbers of young people be recruited and retained such that a full-scale RCT is likely to be feasible?
Primary outcome	The two primary outcomes of this f-RCT are i. recruitment rates and ii. retention rates. The study will investigate the acceptability and appropriateness of our putative outcome measures for a future definitive randomised controlled trial (d-RCT).
Rationale	Young people with early BPD benefit from good clinical care and targeted intervention, however are regularly missed or mis-labelled. The feasibility trial in the general population would provide initial evidence of variable needs of young people with complex needs, who maybe missed from services as they don't "fit" a model/diagnosis. Workable multi-agency service model proposed in the trial would be a major advance in understanding care pathways regardless of trial outcome.
Methodology	We plan to conduct an f-RCT following the Medical Research Council Complex Interventions Framework.
Sample size	Our pilot work suggests that the sample size (N=60) and timescale for recruitment and randomisation, intervention delivery and for follow-up data collection is appropriately estimated. The sample of the feasibility study is adequate to estimate clinical parameters of recruitment and retention. We will

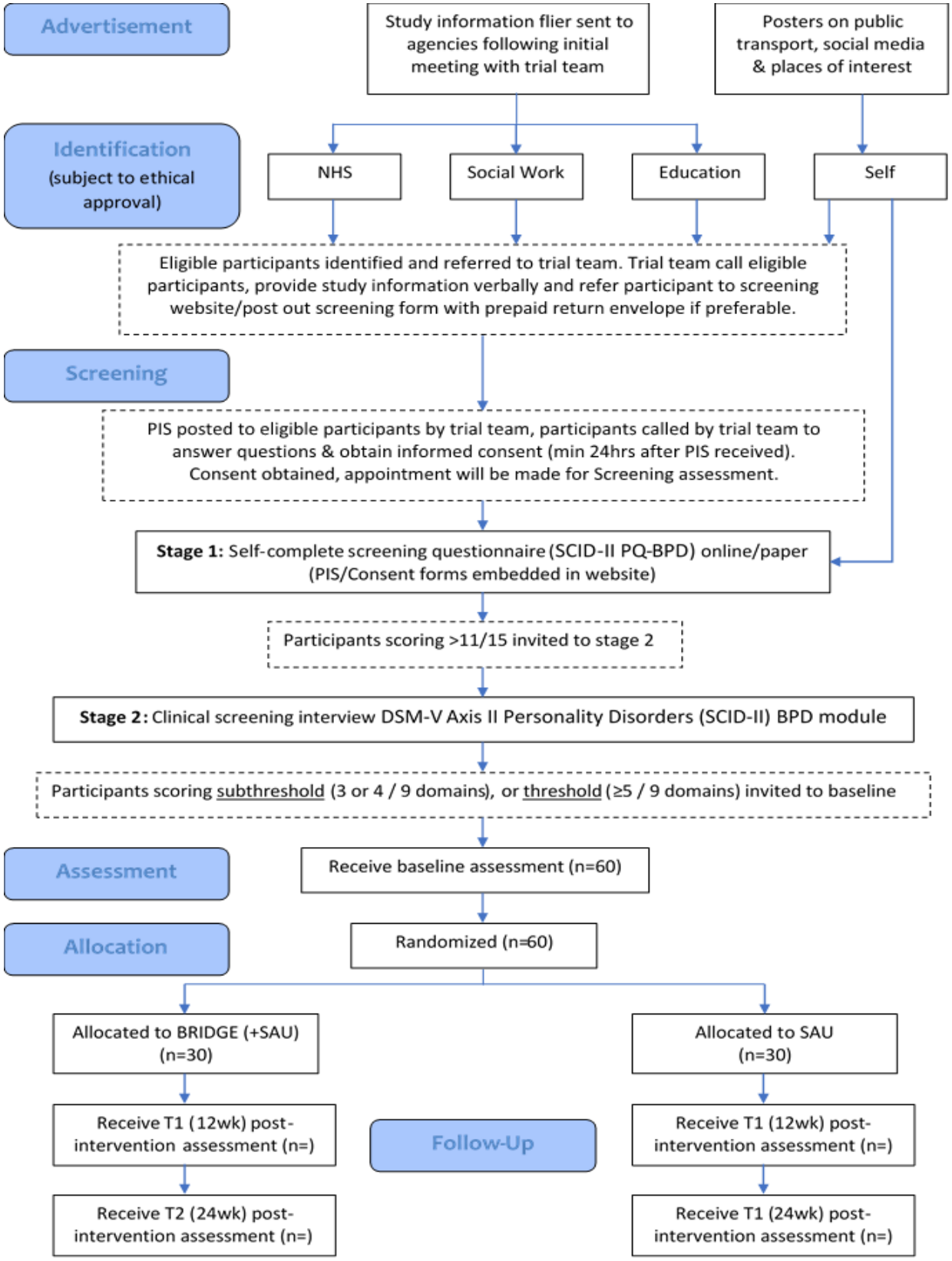
	use the standard deviations of the putative outcome measures used in this study for the power calculations for the definitive RCT.
Screening	The screening would include a two phased approach: Screening Phase 1 : Participants (accessed through a range of clinical and non-clinical settings in Glasgow) will self-complete the brief (15-item) SCID-II PQ-BPD questionnaire. Potential participants can be either referred by a professional in a range of services in Glasgow (e.g. health, social, education) or can self-refer through advertisements in public places: everyone will complete either an online or paper screening assessment. Those meeting the cut off for the SCID-II PQ BPD (>11 out of 15) will be invited to Phase 2. SCID-II PQ-BPD has excellent psychometric properties and is used as a screening tool for BPD in outpatient youth. At Screening Phase 2, all potentially eligible participants will be invited for a short (< 30 minutes) interview conducted using the Structured Clinical Interview for DSM-V Axis II Personality Disorders (SCID-II) BPD module. The eligibility criteria for the study will be those who meet subthreshold (3 or 4 out of 9 domains) or threshold (5 and above out of 9 domains) criteria on the SCID-II DSM-V, for intake to the BRIDGE study before randomisation.
Randomisati	On completion of the baseline data collection, consenting participants will be individually randomised 1:1 to BRIDGE plus service-as-usual (SAU) or SAU.
Inclusion Criteria	- Cut off score of 11 out of 15 on the self-reported SCID-II BPD questionnaire AND subthreshold (3 or 4 out of 9 domains) or threshold (5 and above out of 9 domains) criteria on the SCID-II DSM-V (BPD Module) - Aged between 14 and 24 years, until their 25th birthday
Exclusion Criteria	- Currently receiving psychological/counselling /psychotherapeutic treatment for BPD - Has received previous psychological intervention for Borderline Personality Disorder (BPD)/BPD Symptoms. - Severe or profound intellectual disability, that would preclude full engagement in talking therapy

	- Receiving Intensive psychiatric treatment at the time of study entry, for conditions such as acute psychosis or severe eating disorder - Non-English speaking
Intervention	**Brief, intensive assessment and integrated formulation (BRIDGE)** intervention development has been guided by a) the emerging evidence base for Cognitive Analytic Therapy (CAT) with young people (aged 15-25) with BPD in an early intervention service and b) in collaboration with an established Glasgow intervention programme, called Intensive Support and Monitoring Service (ISMS), used in the Glasgow youth justice system. ISMS has the explicit focus of reaching a shared formulation with the young person and the multi-agency system that supports them. BRIDGE is delivered over 3-6 months and has a three-fold focus: Firstly, an intensive (post-randomisation) assessment, taking up to two sessions, including BPD symptoms, copresenting difficulties, neurodevelopmental profile, life events history and psychosocial functional impact. Secondly, up to 16 sessions of Cognitive Analytic Therapy (CAT)14. Thirdly, development of a shared formulation with a multi-agency group; further development of the shared formulation with the young person, using CAT principles (Reformulation, Recognition and Revision) and, where clinically applicable, their family and service-providers. ***Services as Usual (SAU)*** For participants randomised to SAU, a routine letter of their participation will be shared with their service provider(s), including their GP. SAU, is likely to range from social services, mental-health services, forensic services to no services in some cases. Pathways to care and service involvement will be mapped and described for each participant. Treatment fidelity to SAU will therefore not be assessed, but the nature and intensity of SAU in different contexts will be described in detail through the qualitative process evaluation.
Statistical Analysis	Analyses carried out in the f-RCT will remain blinded. Recruitment, retention rates and the BRIDGE sessions attended will be calculated with 95% confidence intervals (CI). A simple descriptive analysis of recruitment / retention relative to eligible / approached population will be conducted. While

	underpowered, between-group change in each measure after adjustment for baseline will be estimated using analysis of covariance (ANCOVA). Economic Analysis and Treatment fidelity: For the economic analysis, data will be collected on cost of delivering the intervention in addition to participant use of health, personal social services and broader educational and societal resources.

2 Trial/study summary

2.1 Participant flow diagram



2.2 Trial summary

This project is the first step in testing a new intervention programme, called BRIDGE (Brief, Intensive Assessment and Integrated Formulation), for young people early in the course of Borderline Personality Disorder (BPD). The BRIDGE Project will help us find out whether we can do a much bigger study in the future that will tell us whether BRIDGE works well. BPD is characterised by long standing difficulty in managing emotional responses, personal relationships, impulse control and self-image. Research shows that individuals with BPD may experience discrimination and resulting stigmatisation by both the public and health care professionals. Many adolescents and young people with complex needs and high suicide risk are left under-diagnosed and untreated. As a result, young people with BPD are frequently not in education or training and experience challenging relationships with friends and families. The overall aim of the study is to assess the possibility of providing a treatment programme for young people with BPD symptoms in the general population, who may or may not be accessing any mental health services. First, we need to see whether young people are comfortable with random allocation to BRIDGE (AND service as usual) or Service-as-usual (ALONE) (a bit like tossing a coin). Second, we need to find out whether enough young people want to be involved. Third, whether we can find out the information we need about them and can follow up enough young people later. The proposed study will try to find these things out, so that we can design a future, bigger, study to find out whether BRIDGE is good value for young people with BPD.

3 Introduction

3.1 Background

Borderline personality disorder (BPD) is diagnosed on the basis of a pervasive pattern of instability of interpersonal relationships, self-image, and mood as well as marked impulsivity. It is a controversial diagnosis in young people, yet those with symptoms meeting criteria for BPD are frequently under-diagnosed, untreated, are not in employment or training and estranged from their families (1).

BPD is the most common of personality disorders: in an adult population of 18 to 64-year olds, 5% meet criteria for early borderline pathology and 1.1% meet full threshold criteria (2). BPD patients have complex needs and high suicide risk, high rates of psychiatric care, social service use , psychosocial morbidity and functional impairment (3), co-morbid mental health difficulties such as depression and substance misuse (2) and reduced life expectancy (4). BPD patients are typically seen in long term outpatient care or in crisis settings, increasing the potential for iatrogenic harm and worsening the stigmatisation of BPD (5). There is now good evidence that early intervention for BPD in young people can mitigate these negative long term outcomes (6),

yet young people with BPD are often left untreated and clinically unsupported and are less likely to make transition to adult mental health services (7). The implications of this neglect is long term, evident through poor social (3) and vocational functioning (8), and potential intergenerational harm.

Young people with the persistent, complex needs characteristic of BPD – i.e. those with the poorest functioning and most complex psychiatric presentations - are often out of services by age eighteen (7). Barriers to diagnosis and treatment of BPD in young people include the myths that BPD diagnosis implies permanent disability in young people, will lead to clinical and self-experiential discrimination (9), and to widening social, health and occupational disadvantage. There is evidence from randomised controlled trials (RCTs) for the effectiveness of specialised psychotherapies for BPD in adults(10) and more recently in young people (6), but 1) effects are small and unstable at follow-up and 2) do not match the scale of the problem 3) the interventions with demonstrable effect are expensive and 4) may not be scalable at a population level.

3.2 Rationale

The worldwide social and health inequality gap is widening due to Covid-19 and will have serious implications for this most vulnerable group. Scalable approaches to mitigate the long-term psychiatric and social effects of BPD, for the benefit of the whole population, is a public health priority now, more than ever (11). This study builds on pilot work demonstrating that multi-modal recruitment methods, with excellent service user consultation, can achieve high recruitment rates of young people considered hard-to-reach. Having previously demonstrated effective recruitment from within this population, the present study seeks to assess the feasibility of conducting a randomised controlled trial of a brief intervention programme for young people aged 14-24 with sub- or full- threshold BPD, (i.e. ‘early BPD’) in the general population of Glasgow, Scotland.

Primarily, we want to find out if recruitment and retention rates to a brief intervention for BPD symptoms in young people, are adequate to suggest a future full-scale RCT would be possible. Furthermore, we seek to investigate the acceptability and appropriateness of accepted outcome measures for a future definitive randomised controlled trial (d-RCT) which include, at the two follow-ups: [i.] psychosocial functioning [ii.] Quality of life [iii.] emotional regulation [iv.] severity of depression [v.] impulsivity [vi.] severity of self-reported BPD symptoms. We will also attempt to capture care pathways for all participants, for the purposes of future modelling of health economics impacts, in relation to putative quality of life and functional outcomes measures. The findings will inform whether to progress to a definitive RCT and, if so, the design of a definitive trial of the BRIDGE intervention for the researchers to take forward to a large funder. It will also provide a more robust level of medium term evaluation of a BPD intervention for this population

than has previously been available, aiding practitioners and service managers in their decisions relating to BPD service provision.

Timeliness:

There is now good evidence that early intervention for BPD in young people can mitigate these negative long-term outcomes, yet young people with BPD are often left untreated and clinically unsupported and are less likely to make transition to adult mental health services. There is evidence from randomised controlled trials (RCTs) for the effectiveness of specialised psychotherapies for BPD in adults and more recently in young people, but 1) effects are small and unstable at follow-up and 2) do not match the scale of the problem 3) the interventions with demonstrable effect are expensive and 4) may not be scalable at a population level.

NICE guidelines for BPD recommend that people with BPD should not be excluded from any social and health care services but, in practice, BPD sufferers experience discrimination and disengagement from specialist services which perpetuates social and health inequalities.

The feasibility trial is a first to recruit young people with BPD symptoms, from the general population, who may otherwise be missed from specialist mental health services, especially in the current context of the pandemic, where the social and health inequalities are widening. By providing a treatment programme, which has an emerging evidence base in early intervention for BPD, the trial adds to the existing gaps in a) early identification (and description of variable needs) of BPD in the general population b) early intervention for young people through multi-agency work c) understanding care pathways regardless of trial outcome to reduce health inequalities for the vulnerable young people.

Relevance

Societal and professional attitudes to personality disorders, and the service provision that follows from these attitudes, have an important part to play in how services are delivered. One approach to furthering understanding of complex social/service delivery is ‘syndemics’, the term given to the co-occurrence of multiple, inter-related health problems at the individual- and population-level, developing and being sustained by harmful/unhelpful social contexts. Currently, BPD is viewed by many clinicians as intractable, entirely “trauma-related” and, where specialist services exist, treatment provision is delayed and limited to a few. Our own pilot study (‘Pathways study’) and work from other groups has shown that, despite their high psychiatric risk, young with BPD symptoms are less likely to be assessed/treated and often fall into the gap between child/adolescent and adult mental health services.

Our syndemics approach is our key methodology for ensuring excellent interdisciplinary working. Syndemics is embedded within the research methodology, the multi-agency intervention

approach, our international network of collaborators, and the central role of young people at all stages of study design, delivery and dissemination

4 Trial objective(s)

4.1 Objectives

To assess the feasibility of conducting a randomised controlled trial (f-RCT) of a BRIDGE, a brief intervention programme for young people (age 14-24) with early BPD (sub-threshold or threshold) in the general population of Glasgow, Scotland.

4.2 Primary outcome measures

1. Are young people early in the course of BPD willing to be randomised to BRIDGE (AND service as usual) or service as usual (ALONE).

2. Can sufficient numbers of young people be recruited and retained such that a full-scale RCT is likely to be feasible in the future?

4.3 Secondary outcome measures

1. How acceptable are the trial processes and interventions to the participants?

2. Can data systems be set up for assessment of both clinical and health economic outcomes in a future definitive randomised controlled trial (d-RCT)?

3. Does the trial need adapting for participants in different settings (process evaluation and qualitative interviews)?

The putative outcome measures for baseline and follow-up assessments have been selected after consulting the Delphi report from International Committee for Harmonization of Outcome Measures for Personality Disorder (http://www.netscc.ac.uk/hsdr/files/project/SDO_FR_08-1404-083_V0 1.pdf).

The f-RCT will investigate the acceptability and appropriateness of these measures for a future d-RCT which include, at screening/pre-randomisation: SCID-II PQ-BPD; SCID-II DSM-V (BPD module); KIDSCREEN10; Pathways to Care and Demographics. Post randomisation: Mini International Neuropsychiatric Interview (MINI) 7.0.2 (18yrs+) and the Mini International Neuropsychiatric Interview (MINI-KID) 7.0.2 (under 18yrs); Adverse Childhood Experiences Scale; Autism Symptoms adolescents (ASSERT); Adult ADHD Self-Report Scale (ASRS). Baseline and follow-up: Borderline symptoms list (BSL-23); Sheehan's Disability Scale (SDS); Difficulties in

Emotional Regulation Scale-SF; Patient Health Questionnaire-9; Quality of Life Questionnaire (EQ-5D);ICECAP-A; Suicidal Ideation Scale; Vocational and Educational functioning.

5 Trial design

5.1 Design

This proposed feasibility randomised controlled trial (RCT) will follow the Medical Research Council Complex Interventions Framework (Figure 1). We will randomise young people with symptoms of early BPD to BRIDGE (AND service as usual) or service as usual (ALONE) and explore aspects of feasibility using qualitative and quantitative methods. This will allow us to assess the feasibility of recruitment and retention of a sufficiently representative sample for a substantive RCT and help us determine the likely size of such a future definitive RCT.

5.1.1 Participant recruitment

Sixty young people (age 14-24) from Glasgow, experiencing symptoms of early BPD, will be recruited. Participants will be recruited through the following channels (approval dependent);

- Referral from professional within the NHS GG&C (CAMHS, AMHS, GP, A&E)

- Referral from professional within GCC education, social work, forensic services

- Referral from third sector organisations

- Self-referral through advertisements in public places (i.e. transport, libraries, social media)

- Self-referral through re-engagement letter (see Appendix 1). This method of recruitment will aim to recruit participants that have disengaged subseqent to meeting the criteria for the study where consent has been given to be contacted.

Professionals within each of the above services will be made aware of the study through conversations with the trial team. They will then be regularly asked if any patients on their caseload/service users meet inclusion criteria for the study, and can be approached for participation. With potential participants consent professionals will also have the opportunity to discuss potential referrals with the team.

The screening would include a two phased approach:

Screening Phase 1: Participants (accessed through a range of settings in Glasgow) will self-complete the brief (15- item) SCID-II PQ-BPD questionnaire. Potential participants can be either referred by a professional in a range of settings in Glasgow or can self-refer: everyone will complete either an online or paper screening assessment. Those meeting the cut off for the

SCID-II PQ BPD (>11 out of 15) will be invited to Phase 2. SCID-II PQ-BPD has excellent psychometric properties and is used as a screening tool for BPD in outpatient youth.

At Screening Phase 2, all potentially eligible participants will be invited for a short (< 10 minutes) interview conducted using the Structured Clinical Interview for DSM-V Axis II Personality Disorders (SCID-II) BPD module. The eligibility criteria for the study will be those who meet sub-threshold (3 or 4 out of 9 domains) or threshold (5 and above out of 9 domains) criteria on the SCID-II DSM-V, for intake to the BRIDGE study before randomisation.

5.1.2 Intervention

Brief, intensive assessment and integrated formulation (BRIDGE) intervention development has been guided by a) the emerging evidence base for Cognitive Analytic Therapy (CAT) with young people (age 15-25) with BPD in an early intervention service and b) in collaboration with an established Glasgow intervention programme, called Intensive Support and Monitoring Service (ISMS), used in the Glasgow youth justice system. ISMS has the explicit focus of reaching a shared formulation with the young person and the multi-agency system that supports them.

BRIDGE is delivered over 3-6 months and has a three-fold focus:

Firstly, an intensive (post-randomisation) assessment, taking up to two sessions, including BPD symptoms, copresenting difficulties, neurodevelopmental profile, life events history and psychosocial functional impact.

Secondly, up to 16 sessions of Cognitive Analytic Therapy (CAT).

Thirdly, development of a shared formulation with a multi-agency group; further development of the shared formulation with the young person, using CAT principles (Reformulation, Recognition and Revision) and, where clinically applicable, their family and service-providers.

5.1.3 Comparison

For participants randomised to Service-As-Usual (SAU), a routine letter of their participation will be shared with their service provider(s), including the GP. SAU, likely to range from social services, mental-health services, forensic services to no intervention will be mapped and described for each participant. Treatment fidelity to SAU will therefore not be assessed, but the nature and intensity of SAU in different contexts will be described in detail through the qualitative process evaluation.

5.2 Procedure

Our three-month pre-trial set-up phase will establish a detailed system for managing referrals and randomisation and network between the various services from whom we would receive referrals (see section 5.1.1), including any self-referrals/completed online questionnaires. All potential participants will receive a 'Participant Information Leaflet' and a 'Trial Consent Form' prior to Screening 1.

On completion of the Participant Information sheet (online or paper format) and consent form from young people (age 14-24), and from parents and assent from children (age 14-16 who are judged by a healthcare professional as incapable of providing consent), the trial research team (trial manager and research associate) will ensure eligible adolescents and young people are invited to screening 2 with a clinician, prior to study randomisation. Capacity to consent will be confirmed and documented by a healthcare professional at screening 2, prior to randomisation.

Randomisation will be controlled by the Trial Team at the University of Glasgow, who will randomise patients (1:1) to BRIDGE (+SAU) or SAU. The trial manager will generate a randomisation list to ensure data collector blindness. The randomisation list containing the unique study ID and participant name will be stored in a password protected file within the Trial Team's private Microsoft Teams channel (following GDPR guidelines at the university of Glasgow secure server), and access will be restricted only to those members of the research team who will remain unblinded throughout the study. A log of access will be maintained.

All participants consenting to participate will be invited to complete assessments, post randomisation, at baseline, 12 and 24 weeks follow up. A minimum data set of care pathways will be described at baseline and follow-up for all participants, for the purposes of future modelling of health economics impacts, in relation to putative quality of life and functional outcomes measures. Case-study methodology will be used to understand individual contexts, involving qualitative interviews with fourteen young people (seven from BRIDGE intervention and seven from SAU's) and, where possible, their parents and relevant service providers. Topics will include acceptability of the three elements of BRIDGE, perceived mechanisms of change and exploration of requirements for data collection for a future d-RCT, including for future health economic evaluation.

5.3 Measures

The putative outcome measures for baseline and follow-up assessments have been selected after consulting the Delphi report from International Committee for Harmonization of Outcome Measures for Personality Disorder (http://www.netscc.ac.uk/hsdr/files/project/SDO_FR_08-1404-083_V0 1.pdf). The f-RCT will investigate the acceptability and appropriateness of these measures for a future d-RCT which include, at screening/pre-randomisation: SCID-II PQ-BPD;

SCID-II DSM-V (BPD module); KIDSCREEN10; Pathways to Care and Demographics. Post randomisation: Mini International Neuropsychiatric Interview (MINI) 7.0.2 (18yrs+) and the Mini International Neuropsychiatric Interview (MINI-KID) 7.0.2 (under 18yrs); Adverse Childhood Experiences Scale; Autism Symptoms adolescents (ASSERT); Adult ADHD Self-Report Scale (ASRS). Baseline and follow-up: Borderline symptoms list (BSL-23); Sheehan's Disability Scale (SDS); Difficulties in Emotional Regulation Scale-SF; Patient Health Questionnaire-9; Quality of Life Questionnaire (EQ-5D);ICECAP-A; Suicidal Ideation Scale; Vocational and Educational functioning.

All the measures will be incorporated into a user-friendly questionnaire "book" and participants will have the option of completing on paper, in a telephone interview, or a mixture – a technique that has worked well in previous studies. These measures will be conducted, blind to group status, before and 12 and 24 weeks post randomization.

Analyses carried out in the f-RCT will remain blinded. Recruitment, retention rates and the BRIDGE sessions attended will be calculated with 95% confidence intervals (CI). A simple descriptive analysis of recruitment / retention relative to eligible / approached population will be conducted. While underpowered, between-group change in each measure after adjustment for baseline will be estimated using analysis of covariance (ANCOVA).

5.4 Process evaluation

Case-study methodology will be used to understand individual contexts, involving qualitative interviews with fourteen young people and, where possible, their parents and relevant service providers. Topics will include acceptability of the three elements of BRIDGE, perceived mechanisms of change and exploration of requirements for data collection for a future d-RCT, including for future health economic evaluation.

5.5 Health economics

For the economic analysis, data will be collected on cost of delivering the intervention in addition to participant use of health, personal social services and broader educational and societal resources.

A minimum data set of care pathways will be described at baseline and follow-up for all participants, for the purposes of future modelling of health economics impacts, in relation to putative quality of life and functional outcomes measures.

6 Recruitment details

6.1 Centre and Investigator selection

This is a multi-site trial, with trial office located at the Department of General Practice within the University of Glasgow. The following documents will be in place and copies available in the Trial Master File before recruitment of participants:

- A signed Study Agreement (CI and sponsor signature)
- The approval from the Centre's R&D Department, or organisational approval from non NHS organisations
- Completed Signature List and Roles and Responsibilities document
- Completed contacts list of all site personnel working on the Study
- Consent/assent form and PIS on letter headed paper

The NHSGG&C is included as an identified site for this study as patient notes held by the NHSGG&C will be accessed by the trial team. If remote data collection/therapeutic work is not an option for participants, they will be offered the opportunity to meet at an easily accessible location (e.g. GP surgery or public library). We will follow all local Covid guidance e.g. a phone call will be made to ensure that the participant is feeling well and has no symptoms prior to attending the appointment.

6.2 Trial population

Sixty young people aged 14-24 screening for early BPD, will be randomised in a 1:1 ratio to receive either a) the brief intervention plus service-as-usual or b) service-as-usual alone. Follow up will be 12 weeks and 24 weeks post-intervention. This sample size is adequate to estimate clinical parameters for recruitment and retention. Standard deviations of the putative outcome measures will facilitate power calculations for a future d-RCT.

6.2.1 Inclusion Criteria

- Cut off score of 11 out of 15 on the self-reported SCID-II BPD questionnaire (at screening 1 - see below) AND sub-threshold (3 or 4 out of 9 domains) or threshold (5 and above out of 9 domains) criteria on the SCID-II DSM-V for BPD.

- Aged between 14 and 24 years, until their 25th birthday

6.2.2 Exclusion criteria

Young people meeting the following criteria will be excluded:

- Currently receiving psychological/counselling /psychotherapeutic treatment for BPD

- Has received any previous psychological for Borderline Personality Disorder (BPD)/BPD Symptoms

- Receiving intensive psychiatric treatment at the time of study entry, for conditions such as acute psychosis or severe eating disorder

- Non-English speaking

6.3 Number of participants

A formal sample size calculation is not appropriate for this feasibility trial: Our pilot work suggests that the sample size (N=60) and timescale for recruitment and randomisation, intervention delivery and for follow-up data collection is appropriately estimated. The sample of the feasibility study is adequate to estimate clinical parameters of recruitment and retention. We will use the standard deviations of the putative outcome measures used in this study for the power calculations for the definitive RCT.

6.4 Recruitment and informed consent

Participants can be either referred by a professional in a range of settings in Glasgow (for example, CAMHS, Social work, counsellors) or can self-refer by completing an online or paper screening assessment, the brief (15-item) SCID-II PQBPD questionnaire.

Participants are being recruited from the general population, posters and leaflet's advertising the study will be disseminated at healthcare centres and other key sites guided by out PPIe group. Social media and public transport will also be key areas of advertisement for the study.

Participants who express interest in the study to their referring practitioner or those who self-refer from study publicity will speak to a member of the trial research team. During this call, the participants will be invited to complete a screening questionnaire to determine eligibility for the study.

Following referral, and prior to completion of the eligibility screening form (online or paper format), the trial research team (trial manager and research associate) will ensure eligible adolescents and young people receive the study 'Participant Information Leaflet'. At least 24 hours later, the research team will contact the young person to discuss the study further and seek consent. Informed consent from young people (14-24), and consent from parents of children (age 14-16 who are judged by a healthcare professional as incapable of providing

consent) will be obtained as well as assent from the child. Information, consent and assent procedures will be developed further with input from the first PPIe workshop and in consultation with the Study Steering Committee (SSC). Any consent forms in paper form will be stored at the University of Glasgow trial office in locked cabinets in the rooms with access limited to the research team. No one outside of the research team or appropriate governance staff will be able to find out participant's details, or any other information which could identify them. Any consent forms held electronically will be stored in a secure, password protected study specific folder that is located on the university server facilities with access limited to the study team only. Access to information held on University computers will be password protected. Data will be held for 10 years after the study has been completed, as per the applicable data security and management protocol.

7 Data Collection

All qualitative data will be collected by the experienced researchers trained in the administration of the qualitative interviews. The data will be recorded on the recommended audio recording equipment (e.g. encrypted voice recorders), transcribed in house and digital format of the transcripts stored securely in the electronic study files located on the secured University IT infrastructure.

All quantitative data will be collected via data collection forms developed by the trial team. The study will have data collection system allowing collection of participant's research data where participant will be identified with the study specific participant number only.

7.1 Confidentiality of personal data

The study team works in line with General Data Protection Regulations (2018). All participants will be identified by a study specific number. No names or other personal identifiers will be used in data collection forms. Since name and address information are needed for participant's follow up, the research team will use a master list matching study identifiers to this personal information. However, this list will be password protected, used only by the immediate study team and be kept in a study file accessible to only study team on a secure server within Research Institution. This information as indicated above will be kept separate from the research data, which constitute the research outputs of this study. Copies of consent forms will be kept in a locked filing cabinet in an office with a limited access to research team only. All assessment and questionnaire forms will only bare study specific ID number. Audio recordings will not directly address participants by their names but rather study specific number. Any personal details and any other identifying

characteristics will be removed before being stored in password protected file accessible by the research team only on secured University Servers or the secure trial MS Teams page

7.2 Data Collection forms

A user-friendly booklet will be developed by the trial team incorporating relevant demographic and health economic information, as well as the following psychometrics:

Table 1. Baseline and follow-up assessments for the feasibility trial (The BRIDGE project)

Measure*	Baseline	12 wks	24 wks	What measuring?
Questionnaires				
SCID-II PQ-BPD	✓	✓	✓	BPD symptoms (self-reported)
SCID-II DSM-V (BPD module)	✓	✓	✓	BPD criteria (>3 or above out of 9 domains)
KIDSCREEN10	✓	✓	✓	Overall Functioning
Care pathways record and minimum data set	✓			Demographics, pathways to care
Questionnaires				*Intensive assessment (BRIDGE)*
K-SADS/PL	✓			Assessment of lifetime and present psychopathology
Adverse Childhood Experiences Scale	✓			Adverse childhood experiences
Autism Symptoms adolescents (ASSERT)	✓			Autism assessment
Adult ADHD Self-Report Scale (ASRS)	✓			ADHD symptom checklist
Putative outcome measures of change				*Possible mechanisms*
Borderline symptoms list (BSL-23)	✓	✓	✓	BPD symptom severity
Sheehan's Disability Scale (SDS)	✓	✓	✓	Functioning: work/school, social and family life
Difficulties in Emotional Regulation Scale-SF	✓	✓	✓	Domains of emotional regulation
Patient Health Questionnaire-9	✓	✓	✓	Severity of depression
Quality of life Questionnaire (EQ-5D)	✓	✓	✓	General health related quality of life

ICECAP-A	✓	✓	✓	Wellbeing assessment (Economic Evaluation)
Suicidal Ideation Scale	✓	✓	✓	Suicidal thinking and behaviours (ideation, self-harm, attempts)
Vocational and Educational functioning	✓	✓	✓	School and work (Paid and Unpaid) engagement

** The outcome measures for baseline and follow-up assessments have been selected after consulting the Delphi report from International Committee for Harmonization of Outcome Measures for Personality Disorder (http://www.netscc.ac.uk/hsdr/files/project/SDO_FR_08-1404-083_V01.pdf)*

8 Randomisation

Randomisation will be controlled by the Trial Team at the University of Glasgow, who will randomise participants (1:1) to BRIDGE (+SAU) or SAU (see section 10). The trial manager will generate a randomisation list to ensure data collector blindness. The randomisation list will be stored in a password protected file within the Trial Team's private Microsoft Teams channel, and access will be restricted only to those members of the research team who will remain unblinded throughout the study. A log of access will be maintained.

9 Withdrawal & loss to follow-up

Participants have the right to withdraw consent for participation in any aspect of the BRIDGE trial at any time. The participants care will not be affected at any time by declining to participate or withdrawing from the trial.

A participant may withdraw or be withdrawn from the intervention for the following reasons:

- Withdrawal of consent by participant request
- Any alteration in the participants condition or circumstances which justifies the discontinuation of the intervention in the investigators opinion

If a participant is to be withdrawn, a discussion will take place with the participant – and if necessary with his/her legal representative. The data collected till the point of withdrawal will be retained and this will be clearly documented in participant information sheet and consent form.

The research team will complete a withdrawal form for all participants who consent and subsequently withdraw. This withdrawal form will be retained in the study file. Any queries relating to potential withdrawal of a participant should be forwarded to the Trial Manager.

Upon recruiting participants to the trial, we will gather contact information for them and will explain the plans for future contact. The study does not involve a long period of contact with participants, and therefore we do not expect to lose contact with a high proportion of participants. One of the aims of this study is to determine retention rates.

10 Intervention

Brief, intensive assessment and integrated formulation (BRIDGE) intervention development has been guided by a) the emerging evidence base for Cognitive Analytic Therapy (CAT) with young people (age 15-25) with BPD in an early intervention service and b) in collaboration with an established Glasgow intervention programme, called Intensive Support and Monitoring Service (ISMS), used in the Glasgow youth justice system. ISMS has the explicit focus of reaching a shared formulation with the young person and the multi-agency system that supports them.

BRIDGE is delivered over 3-6 months and has a three-fold focus:

1) An intensive (post-randomisation) assessment, taking up to two sessions, including BPD symptoms, co-presenting difficulties, neurodevelopmental profile, life events history and psychosocial functional impact.

2) Up to 16 sessions of Cognitive Analytic Therapy (CAT).

3) Development of a shared formulation with a multi-agency group; further development of the shared formulation with the young person, using CAT principles (Reformulation, Recognition and Revision) and, where clinically applicable, their family and service-providers.

For participants randomised to Service-As-Usual (SAU), a routine letter of their participation will be shared with their service provider(s), including the GP. SAU, likely to range from social services, mental-health services, forensic services to no intervention will be mapped and described for each participant. Treatment fidelity to SAU will therefore not be assessed, but the nature and intensity of SAU in different contexts will be described in detail through the qualitative process evaluation.

11 Safety Reporting

11.1 Assessment of Safety

For all participants the NHS GGC risk management procedures will be followed and risk assessments will be carried out prior to study visit. For participants held within clinical teams (example, CAMHS), this will be done in collaboration with the participant's clinical team. For participants who may have no service involvement, NHS GGC care planning and safety

procedures will be followed with GP's as point of contact. Participants will also be told if they disclose any risk to themselves or others, we are obligated to share this with their mental health professional/GP. The core research team (trial manager, PhD student, trial therapists) will receive training on risk assessment and management as the ACADEMIC CAMHS team is embedded with specialist children's services, NHS GGC.

11.2 Definitions of adverse events

Adverse Event (AE) – Any untoward medical occurrence in a subject to whom a trial intervention has been offered, including occurrences which are not necessarily caused by or related to that intervention.

11.3 Serious Advert Event (SAE)

Serious Adverse Event (SAE): An untoward occurrence that:

a) Results in death
b) Is life-threatening*
c) Required hospitalisation or prolongation of existing hospitalisation**
d) Results in persistent or significant disability or incapacity
e) Consists of a congenital anomaly or birth defect
f) Other considered medically important by investigator

11.4 Recording and reporting of adverse events

All SAEs will be recorded during the study period to ensure participant's safety and reported to the Principal Investigator (PI). Details of SAEs will be added to the SAE report form stored within the trial site files and followed until resolution. The relationship with the study intervention will be assessed for any unexpected SAEs: if considered related and unexpected these SAEs will be communicated to the PI for review and will be reported to the REC and the sponsor according to standard requirements. The Study Steering Committee will also monitor SAEs to ensure that participant's safety is adequately monitored by those independent to the trial administration.

Any SAE occurring to a research participant will be reported to the main REC (i.e. the REC that gave a favourable opinion of the study) where in the opinion of the Principal Investigator (PI), the event was:

• "**Related"** – that is, it resulted from administration of any of the research procedures, and

• **"Unexpected**" – that is, the type of event is not an expected occurrence.

Reporting to the Sponsor

All Related, Unexpected SAEs (RUSAEs) must be reported to the Pharmacovigilance Office immediately (within 24 hours) using the generic non-CTIMP SAE form which is available from http://www.glasgowctu.org/data/SAE_non-CTIMP.pdf. The SAE form should be completed and signed by appropriately delegated staff. The form should be faxed or e-mailed to the PV Office (pharmacovig@glasgowctu.org) and a copy placed in the Study Site File. If necessary a verbal report can be given by contacting the PV Office on 0141 330 4744. This must be followed up as soon as possible with a signed written (or electronic) report.

If all of the required information is not available at the time of initial reporting, the investigator must ensure that any missing information is forwarded to the PV Office as soon as this becomes available. The report should indicate that this information is follow-up information for a previously reported event.

The Sponsor in liaison with the CI will carry out an assessment of expectedness prior to submission of the event to the REC.

Reporting to the Research Ethics Committee (REC)

The PV office will report all RUSAEs to the ethics committee within 15 days of the PV office becoming aware of the event, via the 'report of serious adverse event form' for non-CTIMPs published on the Health Research Authority web site. http://www.hra.nhs.uk/documents/2015/02/safety-report-form-non-ctimp.docx. The form will be completed by the Sponsor and will be signed by the Chief Investigator prior to submission.

The Data Monitoring and Ethics Committee will be notified of all such events whether considered to be related to the trial interventions or not. The co-ordinator of the main REC will acknowledge receipt of safety reports within 30 days.

11.5 Annual safety reporting

The PI is also responsible for providing an annual progress report to the REC using an NRES "Annual Progress Report form for all other research". This form is available at:

http://www.nres.npsa.nhs.uk/applications/after-ethical-review/annual-progress-reports/

A section on the safety of participants is included in this report.

12 Statistical considerations

12.1 Randomisation

See section 9.

12.2 Sample size

Sixty young people aged 14-24 screening for early BPD, will be randomised in a 1:1 ratio to receive either a) the brief intervention plus service-as-usual or b) service-as-usual alone. Follow up will be 12 weeks and 24 weeks post-intervention. This sample size is adequate to estimate clinical parameters for recruitment and retention. Standard deviations of the putative outcome measures will facilitate power calculations for a future d-RCT.

13 Analysis

13.1 Statistical Analysis Plan

The study will have a comprehensive Statistical Analysis Plan (SAP), which will govern all statistical aspects of the study, and will be authored by the Trial Team in collaboration with a supporting Statistician before any unblinded data is seen.

The Robertson Centre for Biostatistics, part of the Glasgow Clinical Trials Unit, a fully registered UK CRN Clinical Trials Unit, will support and advise on data analysis.

13.2 Main analysis

All statistical analyses will be pre-specified in a detailed Statistical Analysis Plan, to be finalised prior to unblinding of intervention groups, and agreed by the Trial Steering Group.

Analyses carried out in the f-RCT will remain blinded. Recruitment, retention rates and the BRIDGE sessions attended will be calculated with 95% confidence intervals (CI). A simple descriptive analysis of recruitment / retention relative to eligible / approached population will be conducted. While underpowered, between-group change in each measure after adjustment for baseline will be estimated using analysis of covariance (ANCOVA).

Economic analysis

For the economic analysis, data will be collected on cost of delivering the intervention in addition to participant use of health, personal social services and broader educational and societal resources.

Qualitative analysis

Interviews will be transcribed verbatim and subject to a thematic analysis, where re-occurring topics/issues are identified across the dataset using rigorous qualitative analytical techniques.

14 Data management

A Data Management Plan will be developed for the study in line with approved templates, reviewed regularly and all members of the project team will adhere to the plan.

The study team works in line with General Data Protection Regulations (2018). All participants will be identified by a study specific number. No names or other personal identifiers will be used in data collection forms. Since name and address information are needed for participant's follow up, the research team will use a master list matching study identifiers to this personal information. However, this list will be password protected, used only by the immediate study team and be kept in a study file accessible to only study team on a secure server within Research Institution. This information as indicated above will be kept separate from the research data, which constitute the research outputs of this study. Copies of consent forms will be kept in a locked filing cabinet in an office with a limited access to research team only. All assessment and questionnaire forms will only bare study specific ID number. Audio recordings will not directly address participants by their names but rather study specific number. Any personal details and any other identifying characteristics will be removed before being stored in password protected file accessible by the research team only on secured University Servers or the secure trial MS Teams page.

15 Trial closure

The trial will end when the SSC agrees that one or more of the following situations applies:

1) The planned sample size has been achieved, and follow-up is complete;
2) There is insufficient funding to support further recruitment, and no reasonable prospect of additional support being obtained;
3) New information makes it inappropriate to continue to randomise patients to one or other arm of the trial;
4) Recruitment is so poor that completion of the trial cannot reasonably be anticipated.

16 Regulatory issues

16.1 Ethical and research governance

The study will be carried out in accordance with the World Medical Association Declaration of Helsinki (1964) and all subsequent revisions.

The study protocol and all participant documentation and procedures will be submitted to the relevant ethical review board of each study site for approval. As the study may include sites from the NHS, and other public places (e.g. public library) approvals will be obtained for each organisation using their usual ethical review procedures.

Favourable ethical opinion will be sought from Research Ethics Committee in the UK before participants are entered into this clinical trial. Substantial amendments that require review by NHS REC will not be implemented until that review is in place and other mechanisms are in place to

implement at site. Participants will only be allowed to continue in the study once they have provided written informed consent.

- All correspondence with the REC will be retained.
- REC annual reports will be generated as required.
- The PI will notify the REC of the end of the study.
- An Annual Progress Report (APR) will be submitted to the REC within 30 days of the anniversary date on which the favourable opinion was given, and annually until the study is declared ended.
- If the study is ended prematurely, the Principal Investigator will notify the REC, including the reasons for the premature termination.
- Within one year after the end of the study, the PI will submit a final report with the results, including any publications/abstracts, to the REC.

16.2 Consent

Following referral (section 5.1.1), and prior to completion of the eligibility screening form (online or paper format), the trial research team (trial manager and research associate) will ensure eligible adolescents and young people receive the study 'Participant Information Leaflet'. At least 24 hours later, the research team will contact the young person to discuss the study further and seek consent. Informed consent from young people (14-24), and from parents and assent from children (age 14-16 who are judged by a healthcare professional as incapable of providing consent) will be obtained. Information, consent and assent procedures will be developed with input from the first PPIe workshop and in consultation with the Study Steering Committee (SSC). Any consent forms in paper form will be stored at the University of Glasgow trial office in locked cabinets in the rooms with access limited to the research team. No one outside of the research team or appropriate governance staff will be able to find out participant's details, or any other information which could identify them. Any consent forms held electronically will be stored in a secure, password protected study specific folder that is located on the university server facilities with access limited to the study team only. Access to information held on University computers will be password protected. Data will be held for 10 years after the study has been completed, as per the applicable data security and management protocol.

16.3 Confidentiality

Researchers from the University of Glasgow and collaborating partners will collect, store and process all personal information in accordance with the General Data Protection Regulation (2018).

Any data in paper form will be stored at the University of Glasgow and collaborating institutions in locked cabinets in rooms with the restricted access. The study materials in the electronic format will be stored on secured password–protected computers linked to secured University servers. Data in the electronic format will have no links to the participants personal data and only study specific number will be used. The audio recording files will be recorded on the encrypted recording devices and uploaded into project dedicated study folder located on server with the restricted access to authorised researches only. No one outside of the research team or appropriate governance staff will be able to find out participant's name, or any other information that could identify them. All participants will be provided with detailed description of their data handling in Participant Information Sheet.

The data will be stored in archiving facilities in line with the University of Glasgow retention policy of up to 10 years. After this period, further retention may be agreed, or the data will be securely destroyed in accordance with the relevant standard procedures.

16.4 Indemnity

The BRIDGE trial is sponsored by the NHS Greater Glasgow & Clyde. NHS indemnity is provided under the Clinical Negligence and Other Risks Indemnity Scheme (CNORIS).

The NHS has a duty of care to patients treated, whether or not the patient is taking part in a clinical trial, and the NHS remains liable for clinical negligence and other negligent harm to patients under its duty of care.

NHS GG&C will provide indemnity and compensation in the event of a claim by, or on behalf of participants for negligent harm as a result of the study design and/or in respect of the protocol authors/research team.

16.5 Trial sponsorship

The NHS GG&C are the sponsors for the trial.

The NHS R&I GG&C will ensure that the trial is performed in accordance with:

- Conditions and principles of Good Clinical Practice (ICH GCP 1996).
- Declaration of Helsinki (1964 and all amendments)
- UK Policy Framework for Health and Social Care Research V3.3 07/11/2017.
- The General Data Protection Regulation (EU 2016/679, 2016)

- Other regulatory requirements as appropriate.

16.6 Funding

Funder Grant Reference: MQF20\25

Total Cost of Research (Research + NHS costs) £ 224,377.00

The MQMH funding will begin on 16th April 2021.

16.7 Audits & inspections

The trial may be subject to inspection and audit by NHS R&D GG&C under their remit as co - sponsor.

17 Trial management

17.1 Routine Management of Trial

The trial will be co-ordinated from Glasgow by the Trial Management Group. This group normally includes those individuals responsible for the day-to-day management of the trial, such as the PI, other co-investigators and the Trial Manager. The role of the group is to monitor all aspects of the conduct and progress of the trial, ensure that the protocol is adhered to and take appropriate action to safeguard participants and the quality of the trial itself.

The University of Glasgow core research team will comprise; the Chief Investigator, a part-time trial manager, and a full-time PhD student. Two DClinPsy students will also contribute to the trial as part of their research study during their doctoral training.

The core research team will attend weekly project management team meetings, which will help facilitate the standardisation of research procedures/processes and to share experiences and lessons learned. Co-investigators will be kept up to date on study progress through regular meetings with individuals as required, and full co-investigator meetings will be scheduled 3 times annually.

PPIe groups and YPAG will be attended by members of the trial management group, including project managers, co-investigators and/or the process evaluation researcher. Discussions from these groups will be fed back to the trial management group and SSC after every meeting, and group members will have options about how to provide feedback (e.g. reports, meeting minutes, group representative attending TMG or SSC meetings).

17.2 Trial Steering Committee

An independent Study Steering Committee (SSC) will be established and will meet approximately six times during the course of the study, consisting of an independent chair, and three other independent members. The members will be proposed by the CI.

The role of the SSC is to provide overall supervision of the trial and ensure that it is being conducted in accordance with the principles of Good Clinical practice (GCP) and the relevant regulations. The SSC should:

- Agree the trial protocol and any amendments
- Provide advice to the investigators on all aspects of the trial
- Have members who are independent of the investigators, in particular an independent chairperson

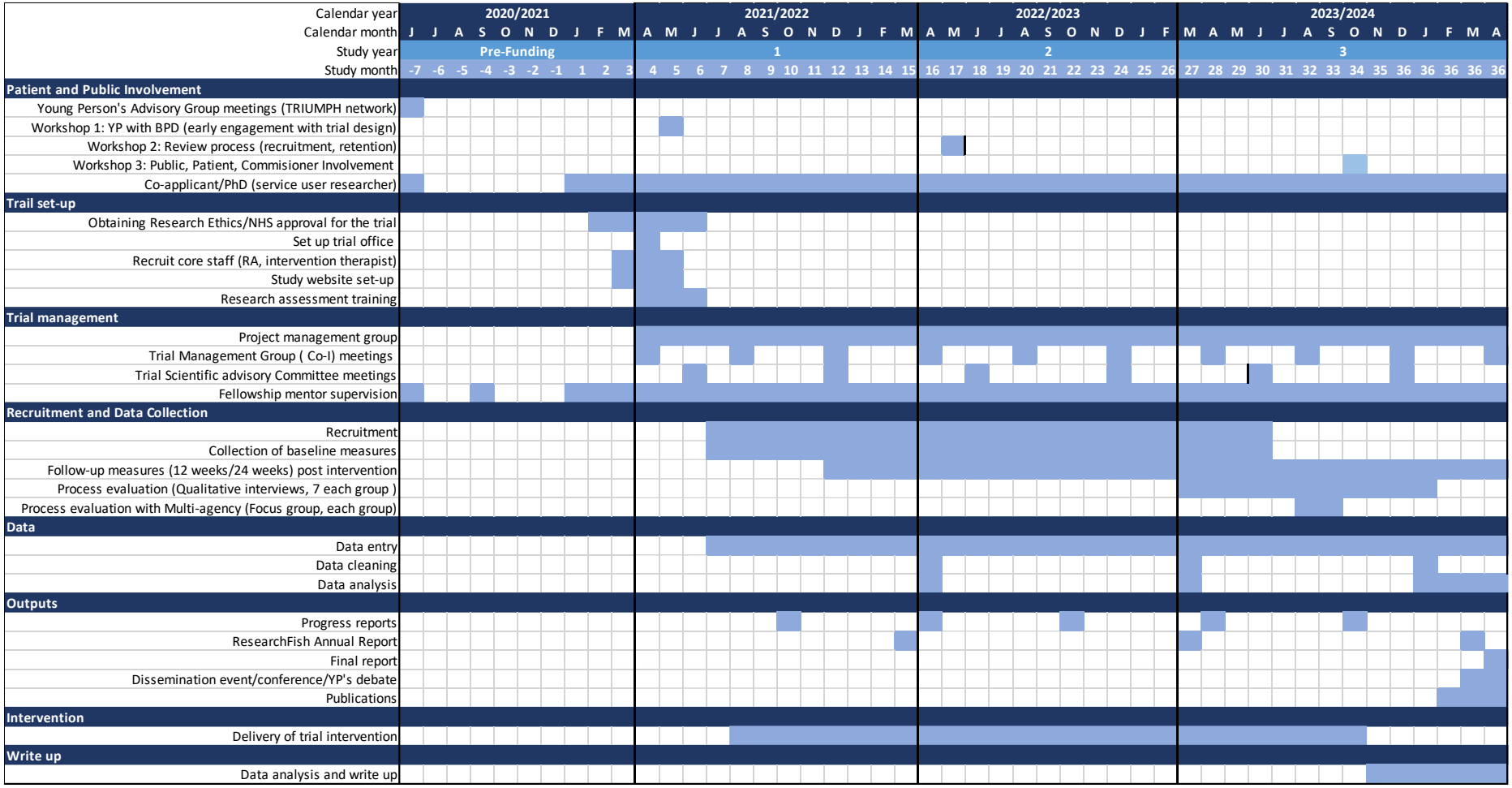
Decisions about continuation or termination of the trial or substantial amendments to the protocol are usually the responsibility of the SSC.

18 Dissemination

We will rapidly report findings in high profile peer-reviewed journals. We have well-developed dissemination routes to policy-makers through our wider academic team's existing voluntary sector partnerships. Our PPIe groups and YPAGs will be key to this engagement work to ensure that Guidelines are presented in a framework of real world journeys through the service landscape.

The parent/carer members of our PPIe group will be instrumental in disseminating our findings to the wider community of young people with symptoms of Borderline Personality Disorder.

19 Timelines



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21 Appendix 1

Dear xxx,

We are contacting you because you were referred to the BRIDGE Project in xxx and you met with us on xxx occasions, with the last follow up in xxx. In these appointments you shared a lot of information about your personal experiences and we value this a lot.

We wanted to get in touch to let you know we have been contacted by eighty young people from Glasgow and we are still contacting people up until December 2023, if you are still interested in being part of the study.

Here's a reminder of what the study is about:-

- Participants are 14-24 year olds living in Glasgow that are experiencing any of these difficulties:- managing their emotions; maintaining relationships; staying in school/college or work.
- The study is exploring a community treatment programme using Cognitive Analytical Therapy (CAT) for young people with features of borderline personality disorder.
- The study isn't a clinical service, we don't give diagnoses.

If you're interested in being part of the study please complete the questionnaire on our website - https://bridgeproject.co.uk/ or contact us on mvls-bridge@glasgow.ac.uk and we can arrange a time to call you back. We will have to ask you some questions again as things may have changed. If we don't hear from you we will try to contact you by phone or text too.

Yours sincerely,

Dr Ruchika Gajwani (Principal Investigator)

The BRIDGE Project

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