Impact of a Distress Brief Intervention on Suicidal Ideation, Suicide Attempts and Self-harm in the immediate, short and longer term.

APPROVED STUDY PROTOCOL

FULL/LONG TITLE OF THE STUDY

Impact of a Distress Brief Intervention on Suicidal Ideation, Suicide Attempts and Self-harm in the immediate, short and longer term.

SHORT STUDY TITLE / ACRONYM

DBI Impact Evaluation on Suicide and Self-harm (DIMES)

PROTOCOL VERSION NUMBER AND DATE

2 2nd September 2025

RESEARCH REFERENCE NUMBERS

IRAS Number:	318172
SPONSORS Number:	P15402
FUNDERS Number:	NIHR 132715

This protocol has regard for the HRA guidance and order of content

DIMES
DBI Impact Evaluation on Suicide and Self-harm

SIGNATURE PAGE

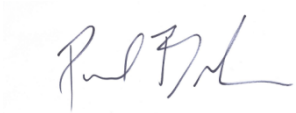
The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Sponsor's SOPs, and other regulatory requirements.

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 publicly 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.

For and on behalf of the Study Sponsor:

Signature:



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Chief Investigator:

Date:
02/09/2025

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Joint-sponsor(s)/co-sponsor(s)	n/a
Funder(s)	National Institute for Health and Care Research (NIHR) NIHR Evaluation, Trials and Studies Coordinating Centre (NETSCC) University of Southampton Alpha House, Enterprise Road Southampton, SO16 7NS Victoria.kimber@nihr.ac.uk

DIMES
DBI Impact Evaluation on Suicide and Self-harm

STUDY SUMMARY

Study Title	Impact of a Distress Brief Intervention (DBI) on Suicidal Ideation, Suicide Attempts and Self-harm in the immediate, short and longer term.
Internal ref. no. (or short title)	DBI Impact Evaluation on Suicide and Self-harm (DIMES)
Study Design	Mixed method evaluation
Study Participants	Adults (aged 16 and over) who access DBI, DBI and NHS24 Staff, and GPs.
Planned Size of Sample (if applicable)	Adults who access DBI survey: 2,700 (some attrition is expected as data collection progresses) Adults who access DBI Qualitative interviews: maximum 75 (some attrition is expected as data collection progresses) Administrative dataset comparator group quantitative analysis: 2500 NHS 24 Mental Health Hub staff focus group: 5 Stakeholder focus groups: 42 – 56 (6-8 per focus group) GP survey: 20
Follow up duration (if applicable)	1 year
Planned Study Period	36 Months from start May 2022 to end April 2025
Research Question/Aim(s)	To understand whether and how DBI can reduce suicidal ideation, suicidal behaviour and self-harm among those presenting to front-line services in distress.

FUNDING AND SUPPORT IN KIND

FUNDER(S) (Names and contact details of ALL organisations providing funding and/or support in kind for this study)	**FINANCIAL AND NON FINANCIALSUPPORT GIVEN**
National Institute for Health and Care Research	£996,035.12
NHS service support costs	£16,380

STUDY CO-APPLICANTS

Professor Rory O'Connor, Chair in Health Psychology, Institute of Health and Wellbeing, University of Glasgow

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Dr Donald MacIntyre, Honorary Reader, Consultant Psychiatrist, Associate Medical Director NHS24, Centre for Clinical Brain Sciences, Division of Psychiatry, NHS Lothian, The University of Edinburgh

ROLE OF STUDY SPONSOR AND FUNDER

NatCen will act as the study sponsor and will be the organisation that takes on overall responsibility for proportionate, effective arrangements being in place to set up, run and report a research project.

The sponsor is also the main contractor for this study and as such will lead on and oversee the production of the protocol study design, conduct, data analysis and interpretation, manuscript writing, and dissemination of results. The sponsor will act as data controller and will be responsible for ensuring that each collaborator complies with Data Protection Legislation. The sponsor will be responsible for ensuring that the study is conducted in line with the requirements of the UK Policy Framework for Health and Social Care: https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/ukpolicy-framework-health-social-care-research/. The sponsor will identify, protect and maintain intellectual property rights for the study and ensure that collaborators keep detailed records of all related activities.

NIHR as the funder has numerous responsibilities in overseeing the conduct of the study. Progress of the Research will be reviewed periodically by NIHR against the specifications on administration and direction of the research and any variation of the contract. The sponsor will provide regular progress reports and an interim report and a final report to the funder for approval as part of the NIHR study monitoring arrangements.

An electronic copy of the approved protocol with a version control table will be submitted to NIHR for approval and published on their website.

ROLES AND RESPONSIBILITIES OF STUDY MANAGEMENT COMMITEES/GROUPS & INDIVIDUALS

A Study Steering Group (SSG) will oversee the study in line with the role, constitution and composition set out in the NIHR Research Governance Guidelines. The SSC will be independently chaired by Nigel Henderson (retired CEO of Penumbra). The SSG will include a health economist, a statistician, a suicide prevention self/harm practitioner, we will also seek representation from the 'Mental Health Collaboration' a Police Scotland, NHS 24 and the Scottish Ambulance Service development group.

A PPI Study Advisory Group will also be established to help ensure that the research is relevant, feasible and validated by lived experience of distress, self-harm, suicidal thoughts and behaviour. The group will be facilitated by the PPI lead and meet nine times during the study to review and feed into the study progress and implementation from a service user perspective.

PROTOCOL CONTRIBUTORS

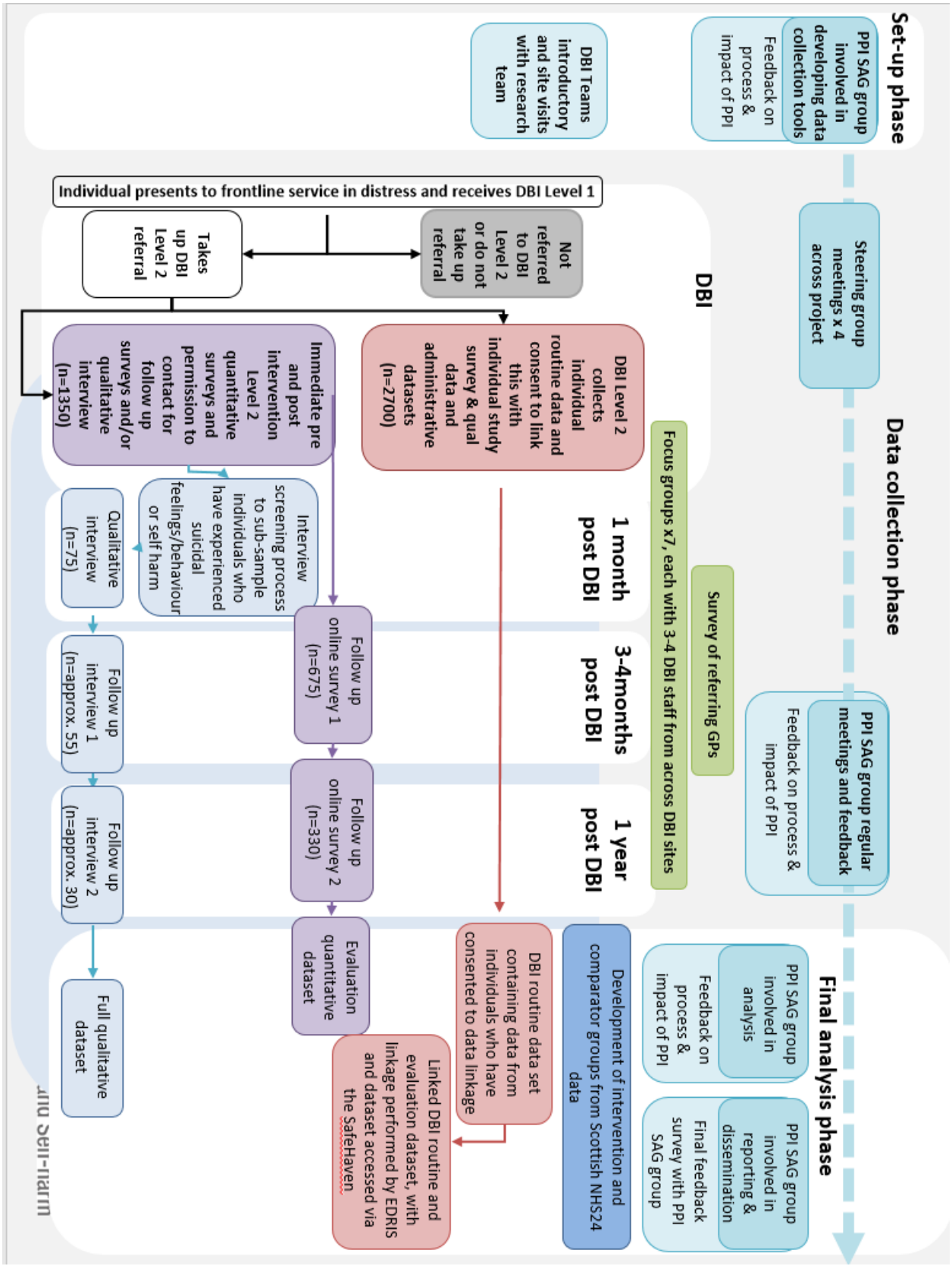
The protocol has been developed by the study PI, study co-ordinator and co-applicants.

KEY WORDS: Evaluation, Suicide, Self-harm, distress, brief intervention.

DIMES
DBI Impact Evaluation
on Suicide and Self-harm

STUDY FLOW CHART

A schematic overview of the study is provided in the flow diagram overleaf.



DIMES
DBI Impact Evaluation on Suicide and Self-harm

STUDY PROTOCOL

Impact of a Distress Brief Intervention on Suicidal Ideation, Suicide Attempts and Self-harm in the immediate, short and longer term.

1 BACKGROUND

Suicide presents a significant challenge across the UK. In 2018[1] there were 784 deaths by suicide in Scotland. Scotland has consistently had the highest recorded UK suicide rate since the 1990's. Nearly 1 in 2 people (44.2%) who died by suicide were in contact with at least one unscheduled care service in the year before death. They were more likely to have had this contact than the general public[2] who did not die by suicide. Nearly three-quarters (73%) had contact with at least one health service in the year prior to death. In Scotland, suicide attempts are most prevalent amongst young (16-24) and middle-aged adults, although men and women in middle-age are most likely to die by suicide[3]; almost half are aged 35-54[4].Younger adults are most likely to self-harm and experience isolation[5]. Self-harm and suicidal ideation are strongly associated with a lifetime risk of suicide[6]. A common driver for all the above is mental distress. Against a background of deteriorating mental health among young people pre-Covid-19, recent evidence suggests that mental distress has increased in the UK population under Covid-19, particularly amongst young adults, women, those employed pre-pandemic and those living with children[7,8].

Distress Brief Interventions Programme

To address the need to improve the response to adults (aged 18+) in distress highlighted by the Scottish Government (SG) Suicide Prevention[9] and Mental Health strategies[10], the Scottish Government (SG) developed the Distress Brief Intervention (DBI). The DBI was developed and delivered by the University of Glasgow (led by co-applicants RO and JMel) from a literature review[11], and consultations with service users and stakeholders. Distress is defined by DBI as '*An emotional pain for which the person sought, or was referred for, help and which does not require (further) emergency service response'*. The DBI pilot programme was launched in 2017.

The DBI programme is a unique approach to supporting those in distress who present to frontline services. It brings SG together with a DBI Central team, local NHS and voluntary DBI provider partnerships, national agencies (Primary Care, Police Scotland, Scottish Ambulance Service, Emergency Departments and NHS24), 3rd sector mental health organisations and University of Glasgow. Six delivery teams operate in four regions: one in each of Aberdeen, Borders, Inverness and three in Lanarkshire. In May 2019, DBI extended to include those aged 16-17. In June 2020, as a response to COVID-19, DBI was extended via NHS24 to gain national coverage. DBI comprises two levels. Level1 (L1) involves trained front-line staff (Primary Care, Police Scotland, Scottish Ambulance Service, Emergency Departments, Social Work and NHS24) offering a compassionate response to individuals in distress and enables referral to a Level2 (L2) service. At L2, individuals are contacted within 24 hrs and offered up to 14 days of community-based, person-centred support from trained staff. DBI explores the nature and cause of individual's distress and how they can manage it in the future. DBI service users co-create a Distress Management Plan (DMaP) with their L2 worker: the previous evaluation suggests many individuals were using their DMaP three months on from DBI intervention. Individuals are then sign-posted to and/or receive support to engage with appropriate follow-up support.

Intervention target length is currently set to two weeks (14 consecutive days) to ensure the service is brief but intervention length is tailored to individual needs. Most people (55%) complete DBI L2 by 14 days, 25% by 21 days and 20% within a month or more. So far DBI

has supported over 10,000 people. Over half (53%) of all individuals referred to DBI between November 2018 and January 2021, were assigned to at least one of the following presenting problem categories: suicidal thoughts (33%), self-harm (12%); thoughts of self-harm (8%); suicidal behaviour (6%); overdose (intentional) (10%). The deprivation profile of DBI service users (as indicated by SIMD) is skewed towards people living in more deprived areas with over half living in the two most deprived quintile areas and a fifth in the two least deprived quintile areas.

Pilot evaluation

A pilot evaluation (2018-2021[12]) of DBI was led by co-applicants ED, JM. The evaluation consisted of a mixed-methods realist evaluation of DBI with adults (>=18 years) in four case study (Health Board) sites in Scotland. Qualitative data (n= 57 interviews/focus groups with staff who delivered DBI, and n= 20 interviews with people who received DBI) and quantitative outcome data collected and analysed. Key study findings demonstrated that the intervention was highly feasible and acceptable to practitioners and people who received the service. Pre-post measurements of distress (CORE-OM 5[13]) demonstrated that most participants' levels of distress reduced following DBI intervention. While DBI did not specifically measure suicidal ideation, suicidal behaviour, or self-harm behaviour, qualitative feedback indicated that without DBI, approximately 10% of study participants felt they would have gone on to complete suicide. Therefore, DBI appears to be filling a critical support gap between unscheduled care, emergency service response and suicide attempts and may help to prevent or break the escalation of crisis to and unhealthy cycles of suicidal behaviour. See Logic Model in supporting documentation.

Existing evidence

A review was conducted using the following databases (2010-March 2021): Cochrane, CINAHL, PsycINFO, Web of Science Core Collection, PubMed and Embase. Keyword searches including the terms psychosocial, intervention or strategy or best practice, suicide attempt and suicide, self-harm or self-injury or deliberate self-harm or self-mutilation or self-injurious were employed. Articles were refined by language (English). The study selection process involved screening titles in the first instance, followed by reading the abstracts. Thirty-six articles were included.

Systematic reviews have investigated the effectiveness of psychosocial interventions to reduce suicidal behaviour and risk or self-harm. These reviews found psychoanalytic and psychodynamic therapies to be effective in reducing the number of patients attempting suicide and hospital admissions[14]. Psychosocial and behavioural interventions that directly address suicidal ideation and behaviour were found to be effective immediately posttreatment and long term[15]. Brief suicide prevention interventions were associated with reduced subsequent suicide attempts and increased follow-up care engagement[16]. Some systematic reviews suggest psychosocial interventions provided in in- and out-patient settings may be effective in reducing future repetition of self-harm following an index episode[14,17,18]. The most comprehensive of these found CBT and problem-solving therapy led to fewer participants repeating self-harm at 6 and 12 months and beneficial effects for secondary outcomes of depression, hopelessness, suicidal ideation and problem solving[18]. Other therapeutic approaches led to less frequent, but no overall reduction in the proportion of individuals engaging in self-harm at 6 or 12 months. Individual case-management and remote contact interventions (e.g., postcards, GP letters, telephone calls) were not associated with a reduction in repetition of self-harm. None of these reviews systematically assessed the role of intervention duration, intensity, setting or practitioner[14,17,18]. A recent narrative evidence synthesis concerning the effectiveness of approaches used in national suicide prevention programs included a meta-analysis of 12 eligible studies on brief contact intervention (BCI) from a systematic review[19]. The study found weakly supportive evidence of the effectiveness of BCI on repeated self-harm, suicide attempt, and suicide, highlighting methodological limitations of current evidence and concluded that further suicide prevention evaluation studies are needed. A review of international distress brief intervention research literature was

undertaken to inform the development of Scotland's DBI programme[12]. It found that despite the existence of international data exploring the effectiveness of DBI and BCI in reducing suicidal ideation, suicidal attempts and self-harm, intervention studies are small in number and scale and vary widely in format, intervention design, target population and outcome measure.

The review of existing evidence confirms that little is known about the impact of brief interventions on suicidal ideation. However, DBI programme evaluation findings suggest that DBI L2 intervention could be preventing suicidal behaviour[12] and further research is recommended. This study will make a significant contribution to filling this knowledge gap. The findings would support the improvement of the current DBI intervention and its wider roll-out to the UK and beyond and inform future development of integrated mental health care and suicide prevention policy and practice.

2 RATIONALE

This study aims to understand whether and how DBI can reduce suicidal ideation, suicidal behaviour and self-harm among those presenting to front line services in distress and crisis.

Suicide prevention has been a policy priority across the UK since the 1990's with some progress made but a clear recognition in recently renewed national policies[9] that suicide prevention action must be improved. Evidence suggests that the impact of the COVID-19 pandemic is likely to be felt widely at both societal and individual levels, impacting on mental health[20] with self-harm and suicide rates expected to increase as the longer-term effects are felt as reflected in recent policy responses focussed on recovery[21]. The review of evidence above and recent NIHR call 18/138 Suicide Prevention in High Risk Groups highlight the scarcity of evidence and need for further research on which statutory and /or voluntary sector interventions are effective in reducing suicide, suicide attempts and self-harm. The Distress Brief Intervention is a significant new approach aimed at reducing distress and self-harm and suicidality embedded in Scotland's suicide prevention[9] and mental health[10] policy plans that has relevance across the UK and beyond. The DBI programme staff are deeply committed to building this study's learning into their continuous improvement programme.

3 THEORETICAL FRAMEWORK

The conceptual framework for this study is grounded within the Integrated Motivational- Volitional (IMV) Model of Suicidal Behaviour[22]. The IMV model is based on the premise that factors associated with the emergence of suicidal thoughts (early life adversity/disadvantage leading to feelings of defeat and entrapment) are distinct from those that influence the transition from ideation to behaviour and understanding the process of ideation to action is crucial to preventing suicide. In the IMV, volitional moderators (e.g., access to means, planning, impulsivity, past suicidal behaviour) govern the transition from suicidal ideation to behaviour. The model proposes that suicidal behaviour is not linear but a dynamic process that for many is cyclical in nature moving from suicidal thinking to attempt and back to thoughts repeatedly over time and that over time the time between thoughts and action becomes less, lessening in turn opportunity to intervene. The IMV model incorporates evidence that those who have a history of suicidal behaviour or self-harm have higher levels of motivational factors. The IMV model is part of the training for staff who deliver the DBI intervention.

With over half of those referred to DBI presenting with self-harm, suicidal thoughts or behaviour, emerging evidence suggests that DBI has potential to fill a critical support gap for such people between unscheduled care and a crisis escalating into self-harm, suicidal ideation or behaviour. A key (not yet published) finding from the first evaluation of DBI is that 10% of those accessing DBI reported that they would have gone on to attempt suicide or continued with their suicidal ideation if DBI had not been available to them. This suggests that DBI may be helping to prevent or break the cycle between a crisis escalating and suicidal / self-harm thoughts and behaviour.

Although the DBI intervention is focused on alleviating the distress associated with a current crisis, as it aims to equip people to better cope with future crisis it has considerable potential to prevent suicidal behaviour in in the short, medium and longer term. Understanding how the DBI intervention has helped people to break the cycle of suicidal thoughts to action or not will provide important insights into how the intervention can be further developed and optimised as a suicide prevention intervention for those with a history of self-harm, suicidal thoughts or behaviour.

4 RESEARCH QUESTION/AIM(S)

This study aims to understand whether and how DBI can reduce suicidal ideation, suicidal behaviour and self-harm among those presenting to front line services in distress and crisis.

The research questions are:

- Does DBI help people who present in crisis and distress with current or previous suicidal ideation, suicide attempts, self-harm achieve better outcomes in the immediate, short and longer term?
- How do these outcomes differ for those with different contributory and protective factors (e.g., financial, relationships, addiction, gambling), in different age groups particularly 16–24-year-olds and 35–54-year-olds), and by gender?
- Are there differences in experience and outcomes for people who present to DBI with suicidal ideation, suicidal behaviour or self-harm compared to other DBI service users?
- What aspects of the DBI intervention contribute to these different outcomes, how and why? (e.g., 24hr response, intensity, problem solving strategies including the distress management plan (DMaP), referral/signposting).
- How does the length of the DBI L2 intervention impact on the above outcomes?
- Does DBI need a Level 3 to follow-up people with suicidal ideation/ suicidal behaviour/self-harm over a longer period? If so, how should this be implemented?
- In what ways might DBI improve its contribution to positive outcomes for people who present with suicidal ideation/ suicidal behaviour/self-harm and how does this apply to other services?
- Is DBI L2 associated with a greater reduction in unscheduled health care use in the year after intervention compared to a comparator group of those who accessed NHS24 for mental health reasons prior to the introduction of DBI?
- What is the health care, social care and third sector resource use for DBI service users over the 12-month period following their DBI L2 intervention?
- What care pathways do GPs use to support people in distress with suicidal ideation, suicidal behaviour and self-harm and what is the resource use associated with this?

4.1 Objectives

The study objectives are to:

- Understand the intervention mechanisms that contribute most to these outcomes and why.
- Focus on the impact on younger people and middle-aged adults.
- Assess the association between L2 DBI intervention and unscheduled healthcare use.
- Elicit the health care, social care and third sector resource use over a 12-month period for people who receive a L2 DBI.
- Identify care pathways used by GPs to support people in distress with suicidal ideation, behaviour or self-harm and estimate associated resource use.
- Produce learning in a format that will inform the continued improvement of DBI and the wider service system.

4.2 Outcome

Key study outcomes include suicidal ideation, suicidal behaviour, self-harm reduction in the immediate (1 month), short (3-4 months) and longer term (1 year).

Secondary outcome measures are improved resilience, self-stigma, mental and physical health in the immediate (1 month), short (3-4 months) and longer term (1 year) and service usage one month and one year prior to and following DBI.

5 STUDY DESIGN and METHODS of DATA COLLECTION AND DATA ANALYIS

5.1 Study design

This is a mixed method evaluation with continuous improvement elements. The design chosen is pragmatic and has the advantage of providing the nuanced understanding required to produce findings with real-world application as intended. Recent evidence suggests that for those using mental health crisis services, what matters to them is that outcomes are measured on a more individual than general level and there is an emerging argument for developing more innovative approaches to studying outcomes in mental health/crisis[23].

Understanding and achieving value in services for people with mental health problems must consider what outcomes matter for those who use services; currently there is no clear consensus between service providers and users on which outcomes really matter in mental health services. Whilst traditional clinical outcome measures help understanding of outcomes at scale, they rarely consider individual life circumstances, the therapeutic value of the connection between service user and provider, compassion, stigma, or basic alleviation of distress[24]. The DBI service is accessed by people from diverse backgrounds with an array of problems that are individual to them and DBI is designed to be tailored to the individual. Therefore, to understand the extent and nature of the impact of DBI on suicidal thoughts, behaviour and self-harm this study will incorporate a combination of quantitative and qualitative measures of outcomes attributable to DBI that capture clinical, therapeutic relationship and individual personal experience and directly informed by PPI.

The original DBI pilot evaluation[12] has shown the feasibility and acceptability of involving DBI providers and those who use the DBI service in evaluation (800+ service user pre and post surveys, 20 service user interviews, 57 staff involved in interviews and focus groups). The study team are experienced in conducting data linkage studies using Public Health Scotland's Unscheduled Care Datamart [24,25,26].

The DBI programme has a standardised routine data system supported by a Public Health Scotland based information analyst Martin McCoy. Martin will be a joint applicant in the Public Benefits and Privacy Panel application for data linkage and facilitate access to DBI routine datasets held by Public Health Scotland. Dr Donald MacIntyre (Associate Medical Director NHS 24) will facilitate access to NHS24 data to identify individual patient records for the comparator group analysis.

5.2 Data Collection

5.2.1 Quantitative surveys for individuals accessing DBI:

Individuals accessing DBI who provide informed consent will be invited to complete a L2 DBI service users survey at their first and final DBI L2 sessions for baseline and immediate outcome data (approximately two weeks apart). These surveys will be administered by DBI L2 staff as described in section 7.1. The surveys are largely quantitative and include a combination of validated scales and bespoke closed questions as well as a small number of open questions to measure the following:

- Impact of assurance of contact 24 hours from referral.

- Level of distress[27], suicidal ideation, suicidal behaviour and self-harm[28], identifying first time/repeat disclosure
- Feelings of entrapment/hopelessness/despair[29]
- Resilience [30]
- Self-stigma[31]
- Health related quality of life [32]
- Perceptions of the DBI aspects, if any, that are most beneficial for above outcomes
- Impact of other different sources of support or life circumstances on the above outcomes
- Health, social care and third sector resource use
- Smart phone and/or email and/or postal address to enable ScotCen research team to administer the 3-month follow-up and 1 year follow-up surveys electronically or address for postal.

Equality and diversity questions are not included in the surveys because demographic data will be linked to survey responses from routine DBI service data for those who consent; this will also help to reduce burden on participants.

At the end of DBI support, participating individuals will be emailed, text, handed in person or posted their second survey by the L2 DBI team.

- Surveys will take 15-20 minutes to complete and can be completed on paper or online and if requested translated versions will be supplied.
- An incentive of £10 will be distributed on completion of each the 4 surveys.
- For paper surveys, L2 staff will write the DIMES study unique identifier onto the paper survey before administering it.
- For online surveys, in their introductory email, individuals will be supplied with their unique DIMES study identifier to use to access their online survey.

Follow-up L2 DBI service users survey for individuals accessing DBI – at 3-4 months and 1 year following the start of the DBI intervention
Using the contact details provided by participants in their consent form and/or their second survey, online or paper surveys will be sent by the ScotCen research team to all evaluation participants at 3-4 months and 1 year following their final DBI session to capture any on-going impact of DBI. In addition to repeating the scales collected in the initial surveys, the follow-up surveys seek to measure help-seeking behaviour improvement, other positive outcomes related to DBI presenting problems/life circumstances e.g., physical health, relationships, addictions, financial, and ask whether further support from DBI would be beneficial, what form this might take and why. Two brief reminders will be sent for each of the follow-up surveys (supporting documents 19 and 20).

A £10 thank you voucher will be provided to participants on completion of each of the four surveys above.

5.2.2 Linkage of individual level DBI L2 individual survey data with routine DBI data
Individual level data linkage between the DIMES participant survey dataset and DBI routine dataset will be undertaken for all evaluation participants who give their consent. This will enable the study team to link outcome data with service user characteristics and DBI intervention activity to facilitate analysis of service user sub-groups and intervention factors such as number of sessions, intervention length and onward referral.

Public Health Scotland (PHS) hold the DBI routine dataset. The linkage will be facilitated by ScotCen supported by Martin McCoy who is responsible for managing the DBI routine datasets at PHS. The linked dataset will be stored securely in the Safe Haven for the study team to access remotely. ScotCen would securely transfer the DIMES participant survey dataset to PHS via Secure File

Transfer Protocol with the DIMES study unique identifier to enable linkage of the survey data to the DBI routine dataset (which also includes the DIMES study unique identifier).

We will also link the above combined dataset to the Unscheduled Care Datamart (UCD) to examine differences in unscheduled care use one year before and after DBI.

Permission to undertake this linkage will be sought from the Public Benefits and Privacy Panel.

5.2.3 Qualitative interviews with individuals accessing DBI

Qualitative interviews with evaluation participants will be undertaken at 1 month, 3-4 months and 1 year following DBI L2 intervention. These in-depth face to face, video or telephone interviews will take place with evaluation participants who have agreed in their second survey (issued at their final DBI L2 session) to be contacted for interview, who have experienced suicidal thoughts, behaviour, or self-harm on referral to DBI L2 and who have been assessed as eligible during the Safe Screening process outlined in section 7.3. The study team researchers undertaking the interviews will be ASIST (suicide prevention) trained. It is planned that up to six attempts will be made to contact those who have agreed to participate in interviews, however this will be reviewed with the Study Advisory Group.

The qualitative interviews will last for approximately one hour and will be semi-structured and focus on:

- The individual's DBI story from referral to exit from DBI and ongoing impact of the DBI intervention
- Perceptions of what aspects of DBI support, if any, were most beneficial in helping with study-specific outcomes (suicidal ideation, suicidal behaviour and self-harm, self-stigma, and resilience) as well as contributory outcomes e.g., financial support
- Impact of other sources on above outcomes (life circumstances, informal support, support from follow-up services that DBI sign-posted to and any other formal sources of support)
- Unintended consequences of the DBI intervention
- Differences in experiences of other services accessed in distress/ suicidality/self-harm
- Perceptions of whether and how support from DBI at the 3-4 month and/or year stage would be beneficial
- Impact of Covid-19 on own distress/suicidality
- Ways in which DBI could be improved

Participants will receive a £25 thank you voucher for their time following each interview.

5.2.4 Comparator group data collection

An RCT study design is not possible for this study. In the Scottish Government's Evaluability Assessment of the DBI Programme[34] a control trial was assessed as an option for the evaluation of the effectiveness of DBI and several major challenges to this were identified. The difficulty in obtaining a control group has been compounded by the national roll-out of DBI L1 in May 2020 whereby all adults in Scotland, if assessed appropriate by NHS24, can now access DBI by phone. From mid-May 2020 to 25th May 2021 there were 3225 NHS24 referrals to DBI Level 2. In the 8-week period up to the 25th May 2021, there were 655 NHS 24 referrals, an average of 82 per week. This national rollout of DBI via NHS24 has made direct comparison against usual care in different regions of Scotland unfeasible. We cannot use other UK or European countries as a control due to the different health, social care and police service systems and policies. Any comparisons with higher level English/UK data would be very difficult to relate any observed differences to DBI. Additionally, other voluntary sector routes for people in distress such as the Samaritans cannot be used as a control as they operate anonymously.

Given the above, we will identify a retrospective comparator group to undertake a comparison with the DBI service user group above using available national data. There are no nationally available

standardised outcomes data for people who present to frontline services that are referral routes to DBI (e.g., police, primary care, A&E) in distress. The Scottish Suicide Information database (ScotSID) only has information on those who have probably died from suicide thus numbers would not be sufficient. ScotSID is part of the Unscheduled Care Datamart (UCD) which links data from NHS24, Scottish Ambulance Service, Out of Hours Primary Care, Emergency Department, Acute and Mental Health services and deaths. Given the limitations set out above, the UCD is the most appropriate place to obtain a comparator group.

Since the inclusion of NHS24 as a Level 1 DBI provider in May 2020, it has become the main referral agency. We will select the comparator group from those accessing NHS24 who were not referred to DBI because they accessed services prior to its roll out throughout Scotland via NHS24. We will request Unscheduled Care Datamart (UCD) records, which links data from NHS24, Scottish Ambulance Service, Out of Hours Primary Care, Emergency Department, Acute and Mental Health services and deaths, for 2018-2019 for people who contacted NHS 24 in October 2019 to March 2020 for mental health reasons. The NHS24 data indicates whether a call went to the Mental Health Hub (MHH). NHS24 receives around 130,000 calls a month and around 3% of these are related to mental health[34]. We will use a call related to mental health as the comparator event and collect information on service use outcomes in the year before and the year after the index call. The comparator event(s) is/are a good proxy for presenting to unscheduled care experiencing mental distress as measured by the distress thermometer used by Level 1 services to assess for referral to DBI. People who received DBI intervention during the same period will be identified through the DBI database held by Public Health Scotland which will be linked to the UCD by eDRIS.

We will also collect demographic information on these individuals e.g., age, gender, ethnicity, SIMD, geographic region, rates of previous unscheduled care use and presence of physical co-morbidity. We will use doubly robust estimation which combines a regression model of the outcome with a model for the exposure (i.e., the propensity score) to estimate the effect of an exposure on an outcome[35].

The use of unscheduled care in the year before and after the selected year for the comparator group and the data collection year for DBI service users will be compared to assess whether use of unscheduled care in the year after is lower for DBI service users. We will also collect data on the primary and (where available) secondary presenting problems as described by each unscheduled care service on the UCD for comparison. The presenting problem descriptors differ across the services. Where listed our analysis will include, but not be limited to:

- Mental health problems
- Self-harm
- Attempted suicide
- And completed suicide

The above comparative analysis will not compare contextually like for like scenarios but will have value as an approximation of the impact of DBI on future use of unscheduled care. We would expect unscheduled care use to be lower in the year after the index event than in the year before due to regression to the mean. If DBI L2 reduces emotional distress and increases capacity for self-management then we would expect the reduction in unscheduled care use (particularly for mental health, self-harm, suicide attempt and completed suicide) to be greater for those receiving DBI intervention than in the historical comparator group. In addition, we will compare, within people who are referred to DBI, whether changes in unscheduled care use are different for those referred for reasons of suicidality or self-harm compared to those who are not.

5.2.5 Qualitative focus group with NHS 24 Mental Health Hub staff

A focus group will be convened with 5-7 staff working in the NHS 24 MHH who have experience of delivering support via the NHS 24 MHH prior to the introduction of DBI as a referral pathway to allow participants to reflect on differences in support prior to, and post, the introduction of DBI. This will

provide us with qualitative insights to complement the comparator group analysis. Recruitment for this group will be facilitated by Dr Donald MacIntyre, Associate Medical Director for NHS 24.

The focus group will cover the differences in the support that that NHS 24 MHH can offer following the introduction of DBI as a referral route, including:

- Approaches used in supporting people who contact NHS 24 MHH with suicidal ideation, suicidal behaviour and self- harm prior to the introduction of DBI as a referral route
- Changes to the approach to supporting people who contact NHS 24 MHH with suicidal ideation, suicidal behaviour and self- harm following the introduction of DBI as a referral route
- Perceptions of what aspects of NHS24 MHH and DBI support, if any, were most beneficial in helping with study-specific outcomes (suicidal ideation, suicidal behaviour and self- harm, self-stigma and resilience) as well as contributory outcomes e.g., financial support
- Impact of other sources on above outcomes (life circumstances, informal support, other formal sources of support)
- Ways in which NHS24 MHH could be improved

5.2.6 Focus Groups with DBI staff

A total of seven focus groups will be held with DBI staff. Those undertaken at the pilot sites (six in total) will be held with DBI staff members, DBI Level 1 service representatives (police, ambulance, and A&E) and management. An additional focus group will be undertaken with representatives of the DBI Central Team leadership and DBI Programme Board.

These focus group discussions will draw on early findings from surveys and interviews and issues raised by the SAG in relation to these to explore staff perceptions of:

- Impact(s) their intervention has on people presenting with suicidal thoughts, behaviour and/or self-harm
- Whether and how they can break down self-stigma and/or enable disclosure of the above
- What aspects of the DBI intervention model they provide contribute most to the above and why
- Contributing factors and barriers to their ability to support people with the above
- Unintended consequences of the DBI intervention
- Perceptions of whether and how follow-up DBI support for people with above problems would be beneficial
- Impact of Covid-19 on the above areas of interest

The draft focus group topic guide will be adapted in line with early findings and input from the Study advisory Group.

5.2.7 Health economic evaluation

To support the future commissioning of DBI, more evidence is needed on the care pathways of people who receive a DBI L2 intervention and their resource use within the health care, social care and third sector. In addition, for people who present in distress to GPs with suicidal ideation, suicidal behaviour and self-harm, there is no clear pathway for how they are currently managed within the health care system. This information is important if we seek to consider the impact the role of the DBI L2 route could have in the stages before unplanned access to care/support as well as following such care/support.

Design: Three concurrent phases of work will be conducted to address these key gaps in knowledge:

- Phase 1: To identify, measure and value DBI L2 delivery and individual health care, social care and third sector resource use over 12 months for DBI service users participating in the study
- Phase 2: To identify the existing care pathways for people with present to GPs in distress with suicidal ideation, suicidal behaviour, and self-harm
- Phase 3: To collect health related quality of life data using a measure suitable for economic evaluation such as the Re-QoL as part of the DBI L2 individual survey

The GP route has been selected as the previous evaluation of DBI pilot sites indicated that at that time 40% of referrals were from primary care in-hours services. This indicates that DBI presents a possible complement to GP care and therefore, understanding the different resources required for the range of care pathway options open to GPs would be important in the future delivery of the DBI service.

Data Collection:
Phase 1: To measure the resource use of participants in the DBI L2 individual survey, we will collect data from participants on their other uses of health care, social care and third sector resources during the one month prior to referral & then at the immediate, 3- and 12-month points. This data will be collected via the same set of questionnaires used in the DBI L2 individual surveys to assess changes in resource use within the study participant group in the form of a before-and-after design.

As a minimum we will seek to collect data on

- Participant resource use of scheduled primary care (post-DBI): GP visits, mental health nurse, counsellor, medications, support groups, social prescribing
- Participant resource use of unscheduled primary care (post-DBI): emergency services, crisis team
- Participant employment status (post-DBI): full days unable to work due to distress

Phase 2: A sample of up to 20 GPs in participating NHS Boards who have been trained to provide L1 DBI will be surveyed to determine the typical care pathway for individuals in distress and at risk of self-harm. GPs will be identified using information provided by DBI Central. GPs will be sent an email by the study team including a PIS and asked if they would be willing to participate in an online survey and given the contact details of the researcher to follow up where consent can be taken before a link to the survey using REDCap[36] will be sent.

Data from the survey will be used to build the 'stylised' or typical care pathway options, these will be reviewed by the wider study team, SSG and SAG before costs are attached to the pathways. The resource use and costs of stylised care pathways for delivery of service will then be compared with the DBI pathway for people presenting with self-harm or suicidal ideation behaviour. These pathways will not consider individual level resource use.

Phase 3: The Recovering Quality of Life (Re-QoL)[32] health related quality of life measure, which has recently been developed specifically for people experiencing mental health difficulties, will be included in the suite of measures presented in the DBI L2 individual survey at the immediate, 3- and 12-month points. Health state utility values will be calculated at each time point to examine trends in the data.

5.3 Data analysis
Survey data analysis will include descriptive statistics and crosstabulation analysis with logistic regression if appropriate. We will compare demographic, referral source and presenting problem characteristics of survey respondents and non-respondents to assess the representativeness of the survey sample and whether any weighting adjustments are required.

Qualitative survey data will be coded using a staged content approach. Qualitative interviews will be summarised, charted and coded using QSR NVivo 12 and analysed with reference to techniques of framework analysis. Focus groups will be analysed using a framework matrix to explore themes across the data[37]. We will explore any differences or similarities in the views of the DBI and control qualitative participants to assess any perceived impact of the DBI intervention, while paying attention to other contextual influences.

The data linkage analysis will assess whether the difference in frequency of unscheduled care in the year post intervention differs between DBI participants and the comparator group by doubly robust estimation[34] adjusted for unscheduled care received in the preceding year. This analysis will include

adjustment for potentially confounding sociodemographic variables. Secondary analyses and likely zero inflation will be assessed. A full Statistical Analysis Plan will be developed prior to the identification of the comparator group. For the health economic analysis, units of each item for all care pathways and for participant resource use will be collated and presented along with unit costs which will be derived from local sources as well as those which are publicly available[38].

A summative data synthesis will be undertaken to draw together the above through a process of triangulation to develop evidence-based insights and conclusions. Throughout the study, the study team and the SAG, will meet to share thematic and theoretical insights from data collection and analysis and develop interpretive connections and points of synthesis. Policy and practice recommendations will be made.

6 STUDY SETTING

Data recruitment and administration of data collection (face to face, by telephone and/or online) will take place at each of the current six DBI service providers based in Inverness, Scottish Borders, Aberdeen and Lanarkshire. These teams are supportive of the study and are already experienced in similar recruitment and data collection procedures used successfully in the original evaluation. Participants will be recruited either at the community setting (e.g., DBI base, café, at home) in which they are meeting their DBI L2 worker or by telephone. Participants will have the option to complete surveys at the DBI base, online at home or on paper. Service user interviews will be either face to face by video or phone at an appropriate and safe place convenient to the participant. Staff focus groups will take place either face to face in a setting convenient to the staff or via a secure online meeting facility.

Staff focus groups will be face to face at a setting convenient to the participating staff members or online.

All other data collection (from GPs and NHS24 Mental Health Hub staff) will be conducted online.

7 SAMPLE AND RECRUITMENT

7.1 Eligibility Criteria

The inclusion criteria for all study participants and the comparator groups are as follows:
DBI L2 individual quantitative surveys:

- All individuals accessing DBI in the first data collection year at participating DBI provider sites aged 16 years or over will be invited to participate.

DBI L2 service user qualitative interviews:

- Aged 16 years or over
- Agreed to be contacted for interview
- DBI service users who have experienced self-harm, suicidal thoughts or behaviour
- Referred to and received at least one supportive contact from a participating DBI L2 service
- Reported thoughts or acts of self-harm and/or suicide at any time within the past 12 months
- Level of literacy that allows informed consent, complete written records in English and participate in interviews

Comparator group:

- Those accessing NHS24 who were not referred to DBI because they accessed services prior to the roll out of DBI throughout Scotland via NHS24.

- People who contacted NHS 24 in October 2019 to March 2020 for mental health reasons.

NHS24 staff interviews:
- Staff who work in the NHS MHH

DBI staff focus groups:
- DBI L2 staff members
- DBI Level 1 service representatives (police, ambulance and A&E)
- DBI local provider management
- DBI Central team leadership and DBI Programme Board members.

GP survey:
- GPs currently operating in Scotland with L1 DBI training.

The exclusion criteria are as follows:

DBI L2 individual surveys:
- DBI service users under the age of 16
- DBI service users for whom participation in the study is not deemed appropriate by DBI staff depending on individual circumstances

DBI service user qualitative interviews:
- DBI L2 service users who have responded to the quantitative survey but have not experienced self-harm, suicidal thoughts or behaviour
- Medically unfit for interview
- Unable to provide informed consent
- A level of literacy that is not sufficient to complete relevant assessment measures, engage with telephone contact and support or participate in interviews and/or are unable to provide contact details.
- Assessed to be at high or imminent risk of suicide before interview

7.2 Sampling

7.2.1 Size of sample and rationale

L2 DBI service users survey sample: maximum 2,700 (some attrition is expected as data collection progresses, n=2,700 for 1st and n=1350 for 2nd DBI surveys, n=675 for 3–4-month follow-up survey, n=330 for 1 year survey). DBI referral numbers suggest that each DBI provider will receive 1000 referrals in 1 year. In the original evaluation, participants were recruited in a similar way with just under half (46%) completing the first survey. For the L2 DBI individual survey in this study participant sample numbers are based on responses gained in the original DBI evaluation including likely attrition rates for follow-up surveys.

L2 DBI qualitative interviews: maximum 75 (some attrition is expected as data collection progresses). Over the course of the 12-month recruitment period an estimated 6000 individuals will be referred to the six participating DBI L2 services. DBI Programme routine data indicates that 45% of referrals to DBI L2 services experience suicidal thoughts, behaviour or self-harm. This suggests that 2700 referrals are potentially eligible for in-depth qualitative interviews. Our target sample size for in-depth qualitative interviews is 75 (3%) and is achievable with well-trained project staff and a £25 gift as compensation for the time to participate in the interviews.

Comparator group quantitative analysis: 2500. The comparator group of those accessing NHS24 who were not referred to DBI because they accessed services prior to the roll out of DBI throughout

Scotland via NHS24 (since the inclusion of NHS24 as a L1 DBI provider in May 2020 it has become the main referral agency) will be selected from the Unscheduled Care Datamart. We will request Unscheduled Care Datamart records for 2018-2019 for people who contacted NHS 24 in October 2019 to March 2020 for mental health reasons.

For the comparator group quantitative analysis, the sample size is based on 2500 people accessing the DBI L2 during the study period. Assuming the model: generalised linear model using binomial family and a logit link with dependent variable 'UCD use in the year after' and independent variables 'UCD use in the preceding year' and 'group' (DBI versus comparator). Estimating the following odds ratios for the model: intercept 0.80, group 0.70, UCD use in preceding year 2.0 and assuming the DBI group represents 10% of the total analysis sample and that the probability of UCD use in the preceding year is about 70% (estimate based on evaluation data) with alpha set to 0.05 we would have over 90% power to test that the odds ratio for 'group' is different to 1.

NHS 24 MHH staff focus group: 5. The sample of 5-7 focus group participants is based on the premise that there is frequent turn-over in staff at NHS 24 and only a few staff members will be able to reflect on the time prior to the introduction of DBI as a referral route.

Stakeholder focus groups: 42 – 56 (6-8 per focus group). It is intended to hold one focus group per site. Given the relatively standardised nature of DBI it will not be necessary to hold multiple focus groups per site. 6-8 participants is a standard and recommended amount of people per focus group to aid discussion.

GP survey: 20. This should be sufficient to enable the generation of stylised pathways that are reflective of current practice. Recruitment of GPs to studies is very difficult due to their limited time so we would not wish to unnecessarily invite higher numbers to participate to minimise burden.

7.3 Recruitment

7.3.1 Study Recruitment Process for Individuals Accessing DBI

Over a period of one year (November 2022 to October 2023), all individuals aged 16 or over who access DBI at the six participating DBI sites will be invited to participate in the study by their DBI L2 worker at their first support session. Due to Covid restrictions DBI working formats have adapted with most DBI practitioners home working and providing support via telephone, video link (although face to face is still an option). Therefore, in most cases, the study will be explained to individuals via phone or video link by the DBI L2 practitioner using the script which covers key points in the Participant Information Sheet (PIS). DBI staff will use their discretion to introduce the survey at an appropriate time or not at all depending on the individual circumstances (e.g., high distress levels, an inappropriate referral).

When introducing the evaluation, DBI practitioners will refer to the introductory text in their Recruitment Guidance which covers the key points in the Participants Information Sheet. They will also ask individuals to read the Participant Information Sheet which covers:

- The purpose of the research
- Who is carrying it out
- What is involved in taking part and that this is voluntary
- Confidentiality and information security information
- What will happen to the information they provide
- Where they can find out more
- How to make a complaint (if needed)
- How to take part
- Details of how to access the privacy notice

- A contact for further information and to notify should they wish to withdraw from the study at any time.

The PIS will include links to the study Privacy Notice and a FAQs page, and a separate Sources of Support Sheet will be also be shared with every individual invited to participate.

For individuals who wish to complete their surveys online, these documents will be included in an introductory email. Participants who would like to complete the survey on a smartphone and have requested a survey link by text, will also be sent this introductory email. For those who prefer to complete their surveys on paper, hard copy versions will be made available at each DBI site to be handed to individuals if the DBI L2 session is face-to-face. For individuals accessing DBI by telephone or video link, the PIS, FAQs page and Sources of Support Sheet would be sent via email or post to potential participants for them to read prior to giving consent. Following this, verbal consent will be recorded by the L2 practitioner at the earliest convenience.

In the second survey, participants will be asked to provide contact details if they agree to be contacted by the survey team to participate in interviews (face to face, by telephone or video). If they do, they will be called by a member of the study team who will ask a set of brief safe screening questions to confirm eligibility and consent to be interviewed. This process is described in detail in section 7.5. As an additional step, verbal consent is also asked for and recorded at the start of the qualitative interviews.

If individuals wish to participate in the study, they will be asked to sign a DBI Participant Consent form. The process for gaining consent is described in section 7.5.

7.3.2 Recruitment of NHS 24 Mental Health Hub staff members

Participants for the comparator NHS 24 Mental Health Hub staff focus group will be identified with the support of Dr Donald MacIntrye, Associate Medical Director for NHS 24. Information regarding the study will be circulated to staff members by the NHS 24 operations manager. Information sheets for NHS 24 MHH staff will be used with this group of participants. **7.3.3 Recruitment of DBI staff to focus groups**

A list of all staff will be supplied by the central DBI team. The research team will use this to identify a sample that includes a range of staff with different levels of experience who they will invite by email to participate in the staff focus groups.

7.3.4 Recruitment of GPs to the GP survey

A list of GPs operating in the study sites will be requested from DBI Central potential GP survey participants will be emailed by the study research team and invited to participate.

7.4 Sample identification

During the first data collection year, all individuals accessing DBI L2 will be invited to participate by their L2 staff members during their first DBI session, or at another appropriate time if necessary (due to their individual circumstances) as determined at the discretion of the L2 DBI staff.

Participants who have agreed to be contacted for qualitative interviews in their second survey will be identified by the research team via their responses to the surveys which will be used to determine their eligibility for interview.

A list of all staff will be supplied by the central DBI team. The research team will use this to identify a sample that includes a range of staff with different levels of experience who they will invite to participate in the staff focus groups.

Comparator group respondents will be identified from Unscheduled Care Datamart (UCD) records as those accessing NHS24 who were not referred to DBI because they accessed services prior to the roll out of DBI throughout Scotland via NHS24.

Participants for the comparator NHS 24 Mental Health Hub staff focus group will be identified with the support of Dr Donald MacIntrye. Information regarding the study will be circulated to staff members by the NHS 24 operations manager.

A list of GPs trained in L1 DBI will be requested from DBI Central. The research team will use this list to select to take part in the GP survey.

7.5 Consent

Consent for individuals accessing DBI to participate in the study

Informed consent will be sought from all participants and confidentiality will be ensured at all times. That participation is voluntary will be detailed in participant facing documents and emphasised by DBI and research staff when speaking to potential respondents.

DBI staff will be trained by the study team and provided with instructions on recruitment and gaining informed consent from service users. All participants will be provided with a Participant Information Sheet, along with details of where the privacy notice and frequently asked questions can be found and research team contact details.

All individuals who wish to participate in the study will be asked to sign a DIMES Participant Consent form. In all instances, if the individual agrees to participate, this will be recorded by the practitioner on the DBI routine information system.

If the participant prefers to complete their surveys online, they will be sent their first survey invite by email, which will include a PIS, Sources of Support Sheet and FAQs and an online consent form which must be completed before participants can go on to answer the survey questions. Participants who would like to complete the survey on a smartphone and have requested a survey link by text, will also be sent this email.

If the participant prefers to complete their surveys on paper and their first DBI L2 session is face-to-face, the individual will be asked to complete the consent form in person and then the DBI practitioner will hand over the paper survey to be completed and returned either directly to the DBI L2 practitioner at the session in a sealed envelope or the individual can take the survey away and post it back to ScotCen directly using an SAE.

If the participant prefers to complete their surveys on paper and their first DBI L2 session is by telephone or video link (this will be the minority of the sample), then the L2 practitioner will first send the PIS, Sources of Support Sheet and FAQs to the potential participant to read. They will then record consent on the paper consent form on their behalf (verbal consent) at the earliest convenience. This will avoid the individual having to return their consent form with their personal details along with their first survey and also reduces the risk that individuals complete their survey but not their consent form. Then the DBI practitioner will send the paper survey along with the Sources of Support Sheet out to the individual who can then return the survey directly to the ScotCen office using an SAE if they still wish to participate.

The consent form will include a series of statements and individuals will be asked to agree to each statement if they give consent including consent for their survey answers to be linked to their DBI routine service data and to the Unscheduled Care Datamart (UCD). The consent form will also request participants' smart phone and/or email address to enable the ScotCen research team to administer the

3-month follow-up and 1 year follow-up surveys electronically (this information will be requested again on the final session survey as a back-up).

If an individual agrees to participate, a unique DIMES study identifier will be allocated to the individual and input to the DBI routine information system. When administering the survey, the unique DIMES study identifier will be inserted into the introductory and subsequent survey emails for the individual to use as their access code for the online surveys. Alternatively, if the participant prefers paper surveys the unique DIMES study identifier will be written onto the participant's paper consent form and first and second surveys by the DBI staff member and written onto the third and fourth surveys by the ScotCen research team before being given or sent to the individual.

As well as individuals being able to withdraw from the study at any time by withdrawing their participation from data collection activities, they can email or call ScotCen to signal their withdrawal and ensure that no further invites to complete surveys or interviews with be made. In addition, DBI staff will inform the research team should they be made aware that any participant wishes to withdraw or is deemed unable to continue to provide informed consent.

If necessary, translated versions of the participant facing documents will be made available to ensure inclusivity.

Consent for individuals accessing DBI to be contacted for interview

As described in section 7.3.1 in their second survey, participating individuals will be asked to provide contact details if they agree to be contacted by the survey team to participate in interviews (face to face, by telephone or video). If they do, one month after the immediate pre- and post- survey responses have been collected, we will contact eligible service users by telephone to conduct a safe screening process. A maximum of six calls will be made, however this may be reduced following review by the SAG. The safe screening will include providing information about the interviews, confirming personal and contact details, a risk assessment to mitigate risk including developing a safety plan and, setting up of the interview.

Where individuals are successfully contacted, study staff will follow a standard protocol which has been developed and used by the Suicidal Behaviour Research Laboratory in many studies with suicidal and vulnerable groups. The protocol covers the following areas:

- Introducing and provide information about the interviews and participation
- Confirming/updating personal and contact details
- Assessing eligibility based on inclusion and exclusion criteria
- Carrying out a risk assessment using a standard proforma and implementing actions to mitigate risk including developing a safety plan
- Organisation of next steps including a suitable date, time, and format/venue for the interview

During the safe screening phone call, a risk assessment proforma will be used to undertake the risk assessment and will include demographic information, history or mental health and suicidal history (e.g., past personal/ family attempt history, current suicidal ideation and intent, presence of a plan, access to means), recent adverse life events, current distress, mood, future thinking, protective factors and supports (current engagement with treatment services/practitioners; family/friends awareness; means restriction; positive relationships at home/life). An overall assessment of low, moderate, high, or imminent risk and a risk mitigation strategy proportionate to the level of risk will be developed. All participants will be encouraged to develop or maintain a safety plan and provided with a sources of support sheet.

Evaluation participants will not be included in the interview sample if they are assessed to be medically unfit for interview; are unable to provide informed consent and/or contact details and/or have a level of literacy that is not sufficient to complete relevant assessment measures, engage with telephone contact and support or participate in interviews, are unable to provide contact details.

As an additional step for qualitative interviewees, a short version of the risk assessment and mitigation protocol will be used prior to each interview to allow interviewers to re-assess eligibility from a risk point of view and to allow the participant a chance to withdraw should they wish to and obtain verbal consent to go ahead with the interview. Immediately after the interview the interviewer will carry out a further brief risk assessment.

Both capacity and consent may change throughout the study period. As far as possible attempts will be made to re-assess capacity and provide opportunities for participants to withdraw should they wish to do so. DBI staff will inform the research team should they be made aware any participant wishes to withdraw or is deemed unable to continue to provide informed consent.

The Participant Information Sheet will also mention that individuals can email or phone the study team at ScotCen to signal their withdrawal from the study.

8 ETHICAL AND REGULATORY CONSIDERATIONS

8.1 Assessment and management of risk

The DBI service developers have established a protocol in relation to intervention delivery to clarify communication and reporting channels for unsafe practice or if any element of the intervention itself proves to elevate individuals' risk of self-harm or potentially result in other unintended negative effects. The protocol involves communicating with the relevant medical directors, commissioners and also Scottish Government contacts, and those agreed in consultation with key staff in each of the four sites.

If the research team become aware of unintended negative effects of the Distress Brief Intervention, these will be initially reported back to the pilot site concerned. Where the unintended consequence could be relevant to other pilot sites, the PI (JM) will inform the pilot site leads of the situation and any suggested mitigating action that could be taken.

As this research involves a vulnerable group of people who have engaged with DBI because they are in distress and may have a history of self-harm or suicidal thoughts and behaviours, it is important to ensure that they are able to participate safely and that risk of harm because of participating is minimised. A Sources of Support Sheet with details of helplines and organisations that can provide support should they need it will be provided to every participant with each survey and at each interview. The PPI lead (training in suicide prevention) will be the named contact within the study team who can speak to participants about taking part and support them to be prepared to participate in follow-up surveys and interviews. We will also use a group email address for such enquiries so that the mailbox can be monitored by our office administrator who will be briefed to enable them to manage basic incoming queries before passing them on to the PPI lead or Principal Investigator should that be necessary.

The safe screening process outlined above will provide a further layer of protection to mitigate against the risk of harm to study interviews participants. A short version of the risk formulation and mitigation protocol will also be included immediately prior to and after each in-depth qualitative interview.

Interviewers will be experienced in conducting qualitative interviews with vulnerable groups and ASIST (suicide prevention) trained. Training for these study staff will be provided by the Suicidal Behaviour Research Laboratory at University of Glasgow led by co-applicants ROC and JMel. The training provided will cover all aspects of the safe screening and selection process, participant recruitment and conducting interviews with vulnerable groups. In addition to the Sources of Support sheet, if an interviewee becomes distressed during the interview, interviewers can provide the interviewee with their local DBI contact number or email and/or with the agreement of the interviewee, let the local DBI sites know the individual has requested DBI to get in touch.

The study design has been very favourably peer reviewed by experts in suicide and self-harm research and lived experience as part of the process of gaining funding from NIHR.

Key risks to the study and how we will address them is detailed in the table overleaf.

Risk	L'hood	Impact	Mitigating actions	Recovery plan
Participation of DBI staff in recruitment of service user participants.	Low	Med	• Previous and planned engagement with local DBI sites on the recruitment process. • Training and instructions on recruitment process. • Support and progress and findings updates throughout. • DBI providers have indicated their support for the study and willingness to recruit for it in writing • Service support costs to cover recruitment time	Offer empathy and trouble-shooting support from the study team with any difficulties that arise during the recruitment process.

Low recruitment of individuals who receive the service to the study.	Low	Med	• Sample numbers informed by recruitment method tested in the original evaluation which demonstrated good levels of service user participation. • PPI Lead consulted with DBI service users on the recruitment process • SAG will identify any ethical and practical improvements that can be made to the process. • Minimizing the amount of data that is collected from this population and have already worked with DBI to ensure that data useful to this research (such as presenting problem) is already collected in a standardised way as routine data codes	At set-up the recruitment process will be refined in collaboration with people who have lived experience of distress and DBI providers.
Loss of participants after recruitment.	Med	Low	• Minimising participant burden • Maintaining contact and interest through a quarterly newsletter, • Building rapport at interviews and • Aiming to have the same interviewer conduct all interviews with an individual • Issuing thank you vouchers for participation	We have accounted for attrition based on previous study with this group and do not expect the attrition levels will be to the detriment of the study.
Prolonged illness, absence or departure of a team member.	Low	Med / High	• Team is from large research units there is additional capacity that can be drawn on in these circumstances. • In the unlikely event that the PI departs ScotCen, she will continue to manage the project.	Regular contact will identify any serious illness early allowing for additional resources to be employed. Approval would be sought from NIHR and the project team for any replacement staff.
Individual becomes distressed during interview.	Low	Low / Med	• Interview screening selection for interview includes full risk assessment. • Interviews conducted one month after referral for a L2 intervention. Reasonable to presume that the distress that related to the referral may have lessened. • Interviewers experienced in working with vulnerable groups and ASIST (suicide prevention) trained with further training on this during the study. • A sources of support leaflet will be provided to every interviewee including access to support from the DBI providers if appropriate. • In addition to the Sources of Support sheet, if an interviewee becomes distressed during the interview, interviewers can provide the interviewee with their local DBI contact number or email and/or with the agreement of the interviewee, let the local DBI sites know the individual has requested DBI to get in touch.	The contingency plan for dealing with sensitive issues or distress will be refined and developed at set-up in conjunction with those with lived experience (PPI Lead and SAG members). The evaluation team bring extensive experience of working with people who are mentally ill and or in distress.
Problems meeting the timetable deadlines.	Low	Low	• Flexible team which can vary the amount of time spent on the to ensure that deadlines are met. • Extensive experience of NHS ethics and PBPP applications and sufficient time built in for these.	Regular meetings to discuss progress, revision of workload, time spent to make sure the project is on track.
Data security breach	Low	Med/ High	• Data collection, storage, transfer and processing will be conducted in line with GDPR. • Researchers will work on linked data in the safe haven.	Researchers will be trained in information security and GDPR. Regular IS audits.

8.2 Research Ethics Committee (REC) and other Regulatory review & reports

Before the start of the study, a favourable opinion will be sought from an NHS REC. The following procedures will apply following NHS REC ethical approval has been gained.

- 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.
- All correspondence with the REC will be retained.
- It is the Chief Investigator's responsibility to produce the annual reports as required.
- The Chief Investigator 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 Chief Investigator will notify the REC, including the reasons for the premature termination.
- Within one year after the end of the study, the Chief Investigator will submit a final report with the results, including any publications/abstracts, to the REC.

Prior to any data linkage, permission will be sought from the Public Health Scotland Public Benefits and Privacy Panel to access DBI routinely collected data for: linkage to the L2 DBI individual survey dataset; to link that combined dataset with the Unscheduled Care Datamart (UCD); to access NHS24 records to select the comparator sample and to link that NHS24 comparator dataset to the UCD.

Regulatory Review & Compliance

Before any site can recruit participants into the study, the Chief Investigator/Principal Investigator or designee will ensure that appropriate approvals from participating organisations are in place. For any amendment to the study, the Chief Investigator or designee, in agreement with the sponsor will submit information to the appropriate NHS REC for them to issue approval for the amendment. The Chief Investigator or designee will work with sites (R&D departments at NHS sites as well as the study delivery team) so they can put the necessary arrangements in place to implement the amendment to confirm their support for the study as amended.

Amendments

If the sponsor wishes to make a substantial amendment to the REC application or the supporting documents, the sponsor must submit a valid notice of amendment to the REC for consideration. The REC will provide a response regarding the amendment within 35 days of receipt of the notice. The PI will be responsible for deciding whether an amendment is substantial or non-substantial for the purposes of submission to the REC and for amending the protocol accordingly. Amendments will be communicated by the PI to the participating organisations departments of participating sites to assess whether the amendment affects the R&D NHS permission for that site.

Any changes to the protocol will be updated on the NIHR website and recorded in the protocol version control table

8.3 Peer review

The funder conducted a high quality peer review process for this study as part of the funding award process. This included the appointment of external, independent peer reviewers based on the following criteria.

High quality peer review

Peer review must be independent, expert, and proportionate:

a) **Independent**: At least two individual experts should have reviewed the study. The definition of independent used here is that the reviewers must be external to the investigators' host institution and not involved in the study in any way. Reviewers do not need to be anonymous.

b) **Expert**: Reviewers should have knowledge of the relevant discipline to consider the clinical and/or service-based aspects of the protocol, and/or have the expertise to assess the methodological qualitative aspects of the study.

c) **Proportionate**: Peer review should be commensurate with the size and complexity of the study. Large multicentre studies should have higher level (more reviewers with broader expertise and often independent review committee or board), and potentially international peer review.

The study gained a very favourable peer review, and the proposal was amended and improved in line with some of the suggestions from the peer review process. The changes made to the detailed research plan for the study proposal (upon which this protocol is based) are clearly documented in the final NIHR funding application.

8.4 Patient & Public Involvement

The development of the DBI programme itself was heavily influenced by people with experience of distress (including those who have been at risk of self-harm or suicide and the LBGTQIA community) via a two-year national engagement programme. They and front -line service providers strongly advocated the need to improve the response to people presenting in distress. Engagement included other stakeholders such as Samaritans, NHS24, Health Literacy, See Me, Care Opinion and DBI provider organisations, LAMH, SAMH, Lifelink, Penumbra, Support in Mind and Richmond Fellowship Scotland. This influenced: the definition of distress; how risk is defined for DBI; structure of DBI in two levels; who DBI would be for; which services would be involved; process for referral to L2; outcome to be achieved; governance arrangements.

Also, during the initial development of the DBI service the University of Glasgow team (co-applicants in this study) undertook engagement meetings with stakeholders. Semi-structured interviews and focus groups were conducted with people with a lived experience and front -line staff during this phase (number of participants = 63). Additional interviews and focus groups were then carried out with younger adults and front-line services staff to inform the extension of DBI to younger adults aged 16-17 years (number of participants = 30).

PPI involvement in the development of this study has and will continue to build on the above and on DBI service user feedback in previous evaluation.

The study idea was ignited by a group of service users who commented in the evaluation that they would have gone on to harm themselves or attempt suicide if it had not been for DBI. As DBI is not an established mental health clinical intervention and most service users have no diagnosis, there is no clear identity around which people who access DBI have naturally coalesced so far and no DBI service user group for the study team to tap into. So, to involve DBI service users in this development of this study we worked with the L2 DBI mental health provider partners to contact previous DBI service users to invite them to be involved. We consulted with these service users (including those who had experienced suicidality) to review the study design and establish how and when people with experience of DBI could effectively be involved in the study, and the support that they would need. This helped to refine the study's PPI plans with insight to service user concerns about, and barriers to, participation (e.g., worries about experiencing distress from reconnecting with issues related to DBI or being asked to participate in PPI at an inappropriate time). It also influenced these changes to the design:

- Inclusion criteria extended to include all those who have used DBI, not only those who DBI staff record as having experienced, or spoken about experiencing, suicidal thoughts and feelings.
- Ongoing recruitment to the PPI Study Advisory Group, so that membership is not limited to those who access DBI early in the research timeline.
- PPI lead will explain the purpose and details of PPI involvement to DBI L2 staff, and DBI L2 staff will identify individuals who may be interested. This allows the invitation to come from someone with whom the individuals have a relationship at a time appropriate to individual circumstances.
- Creation of a PPI Study Advisory Group leader role from within the PPI group. Group leader would be paid at an hourly rate to support and induct new group members and assist with co-ordinating the group.

PPI will be integral to this study; we will invite up to 12 people (seeking to be inclusive of BAME and other minority groups) who have used DBI or have experience of distress, suicide and/or self-harm thoughts or behaviour to join a Study Advisory Group (SAG) meeting nine times during the study (usually online but other modes will be offered). Recruitment will be rolling to allow for drop-out and for new those with more recent experience to join. The SAG will be coordinated by the study PPI lead and a paid PPI Champion and PPI co-lead role will be created to support new members and assist in SAG coordination. Service user members of the SAG (and those attending the SSG) will be reimbursed at a rate of £40 per meeting as a cash or voucher payment allowing those in receipt of social security benefits to receive payment. The paid role of PPI Champion would be at an hourly rate of £20. The PPI lead and PI (JM) are experienced in supporting vulnerable people in research and can help people who become distressed to access support if that should be necessary. The DBI L2 provider partners will be able to provide emotional/practical support to individuals if required. A Sources of Support Sheet will be provided.

The PPI lead and PPI Champion along with the SAG members will help ensure that the conduct of the study is firmly grounded in the lived experience perspective. The SAG will input to the following key areas:

- Study set up - co-creation of informed consent materials, sources of support sheet, bespoke quantitative and qualitative data collection items and input to ethics application.
- Analysis – to help shape the coding frameworks and to feedback on interpretation of findings.
- Dissemination and reporting – input to Gatherings and Final Learning Event situating the study in their experience of accessing DBI. Input to the main report and plain English summary
- Production of a creative findings output from point of view of service users e.g., an animation or short film.
- Two SAG members and the PPI lead will be invited to join the Study Steering Group (SSG).
- The PPI lead and PPI Champion will foster candid and open feedback and ensure that the Study Steering Group decision-making incorporates the views of people with lived experience.

To capture the impact of PPI SAG members will be invited to reflect on each session noting: whether they felt communicated to well, could contribute fully, what if any difference they felt they made, how their involvement impacted them personally and feed this back so that the PPI lead can positively address any issues and improve the process. The PPI lead will keep a log of how the SAG influences the study and SAG members will be invited to complete a brief survey at the end of their involvement.

8.5 Protocol compliance

Accidental protocol deviations can happen at any time. They must be adequately documented on the relevant forms provided to study staff and co-applicants by the sponsor and reported to the Chief Investigator and Sponsor immediately. Compliance will be monitored by the ScotCen research team through regular check-in meetings with participating sites and quality assurance checks made of the

participating sites' recruitment processes. The University of Glasgow co-applicants will monitor the safe screening process and supervise ScotCen and their own staff undertaking the screening. A random sample of early interview transcripts will also be monitored by the ScotCen research team. Each co-applicant is responsible for monitoring their staff in relation to information security legislation and good practice.

Deviations from the protocol which are found to frequently recur are not acceptable, will require immediate action and could potentially be classified as a serious breach. Any breach will be reported to the Sponsor within 24 hours, and this will be submitted to NatCen's incident team and data protection officer who will determine any appropriate actions.

8.6 Data protection and patient confidentiality

All investigators and study site staff must comply with the requirements of the Data Protection Act 1998 and the EU General Data Protection Regulation with regards to the collection, storage, processing, and disclosure of personal information and will uphold the Act's core principles. All ScotCen staff are trained to work to the standards of the ScotCen Quality Management System. The quality management system is interlinked with an Information Security System which is in line with the requirements of the Data Protection Act. ScotCen ensure that all sensitive paper-based information is securely transported between participants and ScotCen (by courier where necessary) and stored in locked filing cabinets. ScotCen only use online or SMS platforms that also conform with ScotCen's data security standards. Portable drives/USB devices are never used for the research. ScotCen is 'notified' under the Data Protection Act 1998 and complies with all its obligations, and also has a DPA committee which provides procedural guidance and advice to researchers. ScotCen has been compliant with ISO 27001 (for Information Security) since October 2008 and achieved certification in May 2010. Each co-applicant institution research team will have a signed Information Security Agreement in place as part of their collaborator agreement with ScotCen which ensures that they are have information security standards in line with those required by ScotCen's ISO 27001 accreditation, GDPR and good practice. ScotCen has been compliant with ISO 27001 (for Information Security) since October 2008 and achieved certification in May 2010. ScotCen is audited externally on an annual basis to maintain its ISO 27001 status.

Only members of the research team will have access to any personal data and as far as possible access will be restricted to a minimum number of research team members necessary to facilitate the processing of raw study data. The study team will work in an integrated way across the study activities although certain elements will be led by different institutions e.g., all institutions will be involved in set-up activities, ScotCen and Glasgow University will share the safe screening and qualitative interviews, University of Stirling will lead on the data linkage and comparator analysis, Glasgow Caledonian will lead on economic evaluation.

Participants who have been recruited into the study and have given informed consent will be assigned a non-identifiable unique DIMES study identifier and all data (paper and electronic) will use this code. As Level 2 participants' codes will be known to DBI Level 2 staff to allow routinely collecting monitoring data to be shared with the research team, a separate code will be allocated to any interview participants for inclusion in published findings. The two ID codes will be held on a master sheet available to the ScotCen research team only.

All study data (questionnaires, digital recordings, data accessed from health records) will be anonymised using a unique DIMES study identifier. All transcripts will be anonymised as far as possible (deletion of any names and study sites). Where held, identifiable data (e.g., contact details) will be held on a separate database (i.e., will not be linked to any data) and will only be used to contact the participant about the study. All data will only be accessed by password protected computers, thus personal and research data will not be transported together at any time. During the study, paper

copies of consent forms and demographic data will be held in a secure, locked storage cabinet at ScotCen. Any paper copies of questionnaires will be held in a separate secure, locked cabinet. These will be anonymised and only a DIMES study unique identifier which will be used to link questionnaires at different time points and demographic data. These will be destroyed two years after the end of the study. All electronic DBI L2 individual survey data will be held on ScotCen servers which are accessed by secure, password protected computers. The analysis of these will be undertaken by the ScotCen study team. The survey data will be stored by ScotCen in a secure archive setting for 5 years to facilitate future analysis and publication of the study material.

The DBI L2 individual survey dataset will be analysed by the ScotCen research team who have extensive advanced statistical analysis experience. This dataset will only be accessible to the ScotCen research team working on this study. The linked DBI L2 individual survey dataset and DBI routine dataset will also be analysed by the ScotCen research team who have extensive advanced statistical analysis experience and by Glasgow Caledonian University team for the economic analysis. This dataset will be stored in the National Safe Haven and accessed remotely by the research teams. Findings will be shared with the rest of the research team via secure FTP.

The University of Stirling will lead on the data linkage and comparator analysis. The datasets will be stored in the National Safe Haven with findings shared with the rest of the research team via the University of Stirling's secure Box system.

The data linkage of the DBI L2 individual survey dataset and DBI routine dataset will be facilitated by ScotCen supported by Martin McCoy who is responsible for managing the DBI routine datasets in Public Health Scotland. ScotCen will securely transfer the survey dataset via Secure File Transfer Protocol with the unique identifier to eDRIS to enable them to link the survey data to the DBI routine dataset. The linked dataset will be held in the secure Safe Haven for the study team to access remotely. The linked dataset will be securely deleted 2 years following the study. This combined dataset will also be linked to the UCD by eDRIS. eDRIS will also be requested to link Unscheduled Care Datamart records for 2018-2019 for people who contacted NHS 24 in October 2019 to March 2020 for mental health reasons. Dr Donald MacIntyre (Associate Medical Director NHS 24) will facilitate access to NHS24 data to identify individual patient records for the comparator group analysis. The linked dataset will be held in the secure Safe Haven for the study team to access remotely. Permission to link study survey data with DBI routine data at an individual level and to link this combined dataset to the UCD will be sought separately from the NHS Health Scotland Public Benefits and Privacy Panel and full details of all data storage, transfer and processing will be scrutinised through that process. In the previous DBI evaluation, permission was granted to link individual DBI service user evaluation survey data with routine DBI data and successfully completed and analysed. The study team are experienced in conducting data linkage studies using Public Health Scotland’s Unscheduled Care Datamart.

The secure linkage of DBI data will be carried out by Public Health Scotland and will comply with all the required governance arrangements for access to such linkages. Routinely collected monitoring data will be accessed by the research team via Public Health Scotland who are collecting this data. No identifiable information will be gathered. The individual's unique number will be used to enable back tracing of data for quality purposes. The linked datasets will be stored by eDRIS in the Safe Haven for 2 years following the study. Public Health Scotland PBPP permissions will be sought for the above arrangements for access to linked datasets.

Qualitative interviews will be analysed by the ScotCen and University of Glasgow research teams who have extensive qualitative analysis experience. ScotCen will create and store the qualitative dataset and will ensure all data is anonymised before it is uploaded to data analysis software. The dataset will be made accessible to the University of Glasgow researchers. Data will be stored on a secure server. Findings will be shared with the rest of the research team at Caledonian University, University of Edinburgh and University of Stirling via secure FTP.

Participants who consent to take part in the study and in follow-up qualitative interviews will be asked to provide an email address and a telephone number or postal address if they wish to be sent paper copies of follow-up surveys (surveys 3 and 4) which will be securely held by ScotCen. The contact details for those participating in surveys will only be accessible by the ScotCen research team. Contact details for those participating in qualitative interviews will only be accessible by the ScotCen and Glasgow University research team. All those who take part in the surveys and qualitative research will be asked to provide details (email address and/or postal address) so that their incentives can be delivered to them. This data will be securely held by ScotCen and will only be available to the research team, programmer and the incentives team that organise delivery of incentives.

Participants will be asked to consent to interviews and focus groups being audio recorded. Where this is not given, field notes will capture the key points made by the participant. Audio recordings of qualitative interviews and focus groups will be made with the consent of participants and will be transferred to the transcription service via a secure, encrypted online system. Other data will be transferred between the research co-applicants and their staff using secure file transfer where data is held in compliance with data protection regulations.

Quantitative data codes will be linked with qualitative data codes by the research team, but this master copy will not be made available to anyone outside of the research team. Direct quotes from participants are likely to be used in reporting the findings of the study. The researchers will ensure that all quotes are non-attributable and details that are reported will be presented in such a way that individual sources cannot be identified. Furthermore, as an evaluation of this nature has the potential to raise sensitive issues related to inter-professional working relationships, the researchers will be mindful of reporting anything that could be construed as inflammatory and potentially cause upset to participants if individual sources were able to be detected.

Recordings of the qualitative interviews will be downloaded onto an encrypted computer and the copy deleted from the audio recorder at the earliest opportunity. A copy of the audio recording will be retained by the research team until the recording has been transcribed and checked, after which it will be destroyed. Transcribing will be done by an external agency which adheres to a confidentiality agreement with ScotCen. Data will be transferred to the transcription service through a secure online system. The digital voice recordings will be securely deleted at the end of the study. The nonidentifying transcripts will be retained by ScotCen in a secure archive setting for 5 years to facilitate future analysis and publication of the study material.

A certificate of destruction of data will be completed by ScotCen and co-applicant institutions when the data has been destroyed. This will be reflected in the information sheets and consent forms. Glasgow University researchers will securely store electronic records of interviewee contact details on password protected secure institution servers and securely delete these one year following the study. Only members of the project team will have access to contact details. Any paper-based notes relating to safe screening or interviews will be stored securely in a locked cabinet or drawer. The University of Glasgow researchers will transfer audio recordings of interviews to ScotCen via FTP to be sent for transcription. Glasgow University researchers will be provided with secure access to the study datasets to facilitate their participation in analysis.

GP survey data will be primarily electronic data which will be stored securely and backed up on secure network drives at Glasgow Caledonian University and stored for 5 years to facilitate future analysis and publication of the study material. Any hard copy data collected as part of the GP survey (e.g., signed consent forms) will be stored in a locked filing cabinet at GCU with access to the research team only. Findings will be shared with the rest of the research team via secure FTP.

8.7 Indemnity

NatCen will provide indemnity for this study to meet the potential legal liability of the sponsor for harm to participants arising from the design or management of the research and of investigators/collaborators arising from harm to participants in the conduct of the research.

8.8 Access to the final study datasets

The DBI L2 individual survey dataset will be analysed by the ScotCen research team who have extensive advanced statistical analysis experience. Data will be stored on a secure network drive that is only accessible to the ScotCen research team working on this study.

The linked DIMES DBI L2 individual survey dataset and DBI routine dataset will also be analysed by the ScotCen research team who have extensive advanced statistical analysis experience and by the Caledonian University team for the economic analysis. This dataset will be stored in the National Safe Haven and accessed remotely by the research teams. Findings will be shared with the rest of the research team via secure FTP.

The University of Stirling will lead on the data linkage and comparator analysis. The datasets will be stored in the National Safe Haven. Findings that have been disclosure checked for external use will be shared with the rest of the research team via the University of Stirling's secure Sharepoint site. Sharepoint is Tier D-compliant. This includes the following information security standards: ISO 27001, ISO 27018, SSAE16 SOC 1 and SOC 2, HIPAA, and EU Model Clauses (EUMC).

PBPP permissions will be sought for the above arrangements.

ScotCen will create and store the qualitative dataset and will ensure all data is anonymised before it is uploaded to data analysis software. The dataset will be made accessible to the University of Glasgow researchers. Data will be stored on a secure server. Findings will be shared with the rest of the research team at Glasgow Caledonian University, University of Edinburgh and University of Stirling via secure FTP.

Glasgow Caledonian will lead on economic evaluation analysis of the GP survey data and will store the dataset on a secure network drive. Findings will be shared with the rest of the research team via secure FTP.

Participating sites will not be able to access the study datasets.

There is no intention to ask study participants to consent for their data to be used in any other study or secondary analysis.

9 DISSEMINIATION POLICY

9.1 Dissemination policy

9.1.1 Ownership of data

The sponsor NatCen will own the data arising from the study. Intellectual property rights are shared as set out in the main contract and collaboration agreements between NatCen and the co-applicants.

9.1.2 Outputs and Publication

On completion of the study, the data will be analysed and where appropriate tabulated and a Final Study Report prepared within one year of the end of the study. The full study report will be peer reviewed and published in the *Health and Social Care Delivery Research* as part of the NIHR Journals Library. All of the participating investigators will have rights to publish any of the study data.

NIHR will be acknowledged in all publications, citing the grant number for the DBI Impact Evaluation on Suicide and Self-harm (DIMES) project, and including the following statement:

This study is funded by the National Institute for Health Research (NIHR) Health Services and Social Care Research programme (NIHR 132715). The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.

Study outputs: Given the range of stakeholders including policy makers, practitioners, academics, service users and the public who may benefit from this work, a wide range of study outputs will be produced during and after the study. Interim findings and study progress will be shared with DBI service providers, user, and carer stakeholders via presentations at two DBI Gatherings during the study, at two study seminars and at a final learning event. An online study newsletter will be produced quarterly. A formal final report will be produced and a plain English version. The study team will publish journal articles and UK and international conference papers.

PPI creative output: The SAG group would be involved in developing a creative output which places the findings of this study in the context of their lived experience of distress and receiving support and highlights the aspects of the findings which are most meaningful to them. The format and content of this output would be decided by the SAG and may involve developing a short film or animation.

Informing and engaging service users, carers, NHS and social care organisations, policy makers and the public: The implementation model for DBI is based on an improvement science approach[39]. This study will feed into the DBI continuous improvement programme. We will do this by participation in two DBI Gatherings (large interdisciplinary and interagency networking meetings, including government and service user organisations to communicate and build DBI programme cohesion) and two smaller Study Seminars of up to 20 DBI staff and stakeholders and a final learning event of up to 60 stakeholders to share progress and interim findings from the study to contribute to DBI's continuous improvement programme. The SAG will have a central role in these activities and will be encouraged to become actively involved in feeding back on study progress and findings from the service user / public perspective. Study participants and DBI service providers will receive the study newsletter. We will use the co-applicant organisation and DBI websites (www.dbi.scot) as well as the DBI Briefing Reports to publish study updates and newsletters and interim findings during the research which will reach a wide range of practitioners, service user and research audiences as well as broader community of interest, including the wider public and key international networks such as the International Initiative for Mental Health Leadership. The Scottish Government has agreed to share study updates and findings through their policy and practice networks. Press releases will be issued by co-applicant organisations to publicise the launch of the research and findings.

Participants can request results, or any data held about them including their contact details and survey or interview data by making a freedom of information request. Results would only be shared with participants after the Final Study Report had been compiled or after the results had been published.

Funding has been allocated to run the Study Seminars and Final Learning Event and an additional, funding has been allocated fund the production of the PPI creative output. Study funds have also been allocated to open access journal fees.

The study protocol will be made publicly available. It is not intended to make any of the datasets for this study publicly available in any format.

9.2 Authorship eligibility guidelines and any intended use of professional writers

All co-applicants and any researchers employed on this study will be granted authorship on the final study report based on the following International Committee of Medical Journal Editor's criteria:

- Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND

- Drafting the work or revising it critically for important intellectual content; AND
- Final approval of the version to be published; AND
- Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

In addition to being accountable for the parts of the work they have done each author should be able to identify which co-authors are responsible for specific other parts of the work. In addition, authors should have confidence in the integrity of the contributions of their co-authors.

All those designated as authors should meet all four criteria for authorship, and all who meet the four criteria should be identified as authors. Those who do not meet all four criteria should be acknowledged.

10 REFERENCES

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