STUDY PROTOCOL

Impact of a Distress Brief Intervention on Suicidal Ideation, Suicide Attempts and Self-harm in the immediate, short and longer term: a mixed method evaluation study protocol

[version 1; peer review: 2 approved with reservations, 1 not approved]

Joanne McLean[1], Jessica Shields[2], Josephine M. Wildman[2], Asiya Hamid[2], Andrew MacGregor[2], Catherine Best[3], Edward Duncan[3], Stacey McNicol[3], Linda Fenocchi[4], Helen Mason[4], Donald MacIntyre[5], Ambrose J. Melson[6], Rory O'Connor[6]

[1]National Centre for Social Research, London, England, EC1V 0AX, UK
[2]Scottish Centre for Social Research, Edinburgh, Scotland, EH2 4AW, UK
[3]Centre for Healthcare and Community Research (CHeCR), University of Stirling, Stirling, Scotland, FK9 4LA, UK
[4]Yunus Centre for Social Business and Health, Glasgow Caledonian University, Glasgow, Scotland, UK
[5]Centre for Clinical Brain Sciences, The University of Edinburgh, Edinburgh, Scotland, EH8 9YL, UK
[6]Suicidal Behaviour Research Laboratory, School of Health & Wellbeing, University of Glasgow, Glasgow, Scotland, G12 8TA, UK

v1 **First published:** 04 Jun 2024, **4**:33
https://doi.org/10.3310/nihropenres.13592.1
Latest published: 04 Jun 2024, **4**:33
https://doi.org/10.3310/nihropenres.13592.1

Abstract

Background

The Distress Brief Intervention (DBI) is a new approach aimed at reducing distress and is embedded in Scotland's suicide prevention and mental health strategies. People in distress can be referred to DBI by front-line healthcare and emergency service staff. DBI promises to make contact within 24 hours and offers people in distress 14 days of compassionate, community-based, and person-centred support. The development of NHS 24, a new specialist National Health Service Mental Health Hub (MHH) embedded in Scotland's urgent care service created a new national route to access DBI.

Protocol

This study is a mixed-method evaluation of the impact of DBI on suicidal ideation, suicide attempts and self-harm in the immediate, short and longer term among people presenting in distress. Evaluation participants include adults who access DBI, DBI staff, individuals who have used NHS 24 MHH, and GPs. A combination of

Open Peer Review

Approval Status ? ✗ ?

	1	2	3
version 1 04 Jun 2024	? view	✗ view	? view

1. **Alexandra Pitman**, UCL Division of Psychiatry, London, UK
2. **Gerd Wagner**, Jena University Hospital, Jena, Germany
3. **A Jess Williams**, King's College London, London, UK

Any reports and responses or comments on the article can be found at the end of the article.

analysis of quantitative survey and linked administrative data, including a comparator group analysis, qualitative interview and focus group data will support understanding of whether and how DBI can reduce suicidal ideation, suicidal behaviour and self-harm among those presenting to front-line services in distress. A survey of General Practitioners and a review of existing literature will be used to model typical care pathways for individuals in distress and at risk of self-harm. Modelled resource use and costs will be explored. All data collected will be triangulated through a summative evidence synthesis to develop evidence-based insights and conclusions to inform policy and practice development.

Discussion

Understanding whether, how and why DBI has helped prevent future suicidal thoughts and behaviour in those with a history of suicidal risk will provide important insights into how the intervention can be further developed and optimised as a suicide prevention intervention.

Plain Language Summary

Understanding how healthcare and voluntary organisations can help people in distress and prevent suicide and self-harm is very important. The Distress Brief Intervention (DBI) was developed in response to the Scottish Government's Mental Health and Suicide Prevention Strategies, which identified a need to improve support for adults in distress. This research aims to find out how DBI helps people in distress to deal with thoughts and feelings of suicide or self-harm and whether it prevents people from attempting suicide or self-harm.

There are two levels of DBI:

At Level 1 frontline staff (e.g., police, A&E, ambulance, and primary care) provide a compassionate response to people who present to them in distress. If these people would like further support, they are referred to the DBI service with a promise of contact within the next 24 hours to start Level 2.

At Level 2 people in distress are offered up to two weeks of community-based support, including wellness and distress management planning, and supported connections to other services.

We collect information in several ways, including:
Questionnaires with DBI Level 2 service users completed immediately before and after receiving DBI, 3–4 months and 1 year after DBI

Interviews with people who have received support from DBI completed 1 month, 3-4 months and 1 year after DBI

Focus groups with DBI staff

Linking the questionnaire answers to information collected by the DBI programme and information collected by the NHS about how people who access DBI use other services

Comparing outcomes for people who use DBI with the outcomes of people in distress who accessed an alternative service (NHS 24 Mental Health Hub)

A group of people who have received support from DBI will advise us on all aspects of the research project. DBI services will use the study findings to improve service delivery.

Keywords
Evaluation, impact, suicide, self-harm, distress, brief intervention, protocol, mixed methods

Corresponding author: Joanne McLean (Joanne.McLean@scotcen.org.uk)

Author roles: McLean J: Conceptualization, Funding Acquisition, Investigation, Methodology, Project Administration, Supervision, Writing – Original Draft Preparation, Writing – Review & Editing; **Shields J**: Conceptualization, Funding Acquisition, Investigation, Methodology, Project Administration, Writing – Original Draft Preparation, Writing – Review & Editing; **Wildman JM**: Writing – Original Draft Preparation, Writing – Review & Editing; **Hamid A**: Writing – Original Draft Preparation, Writing – Review & Editing; **MacGregor A**: Conceptualization, Funding Acquisition, Methodology, Project Administration, Supervision, Writing – Original Draft Preparation, Writing – Review & Editing; **Best C**: Conceptualization, Funding Acquisition, Investigation, Methodology, Project Administration, Supervision, Writing – Original Draft Preparation, Writing – Review & Editing; **Duncan E**: Conceptualization, Funding Acquisition, Investigation, Methodology, Project Administration, Supervision, Writing – Original Draft Preparation, Writing – Review & Editing; **McNicol S**: Writing – Original Draft Preparation, Writing – Review & Editing; **Fenocchi L**: Conceptualization, Funding Acquisition, Investigation, Methodology, Writing – Original Draft Preparation, Writing – Review & Editing; **Mason H**: Conceptualization, Funding Acquisition, Investigation, Methodology, Project Administration, Supervision, Writing – Original Draft Preparation, Writing – Review & Editing; **MacIntyre D**: Conceptualization, Funding Acquisition, Investigation, Methodology, Writing – Original Draft Preparation, Writing – Review & Editing; **Melson AJ**: Conceptualization, Funding Acquisition, Investigation, Methodology, Project Administration, Supervision, Writing – Original Draft Preparation, Writing – Review & Editing; **O'Connor R**: Conceptualization, Funding Acquisition, Investigation, Methodology, Project Administration, Supervision, Writing – Original Draft Preparation, Writing – Review & Editing

Competing interests: No competing interests were disclosed.

Grant information: This project is funded by the National Institute for Health and Care Research (NIHR) under its 'Health and Social Care Delivery Research (HSDR) Programme' (Grant Reference Number NIHR132715). The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.
The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

How to cite this article: McLean J, Shields J, Wildman JM *et al.* **Impact of a Distress Brief Intervention on Suicidal Ideation, Suicide Attempts and Self-harm in the immediate, short and longer term: a mixed method evaluation study protocol [version 1; peer review: 2 approved with reservations, 1 not approved]** NIHR Open Research 2024, **4**:33 https://doi.org/10.3310/nihropenres.13592.1

First published: 04 Jun 2024, **4**:33 https://doi.org/10.3310/nihropenres.13592.1

Introduction

Suicide and self-harm prevention present significant challenges and have been policy priorities across the United Kingdom (UK) for three decades. Annually, 703,000 people die by suicide[1], with 762 people in Scotland dying by suicide in 2022[2]. While some progress on suicide reduction has been made, recently renewed national strategies suggest that suicide prevention action must be improved[3].

Understanding how statutory and voluntary organisations can best help people experiencing mental distress is likely to play an important role in reducing deaths by suicide and episodes of self-harm. Many people who go on to die by suicide have had recent contact with healthcare services: between 2011 and 2021, over three-quarters (78%) of people who died by suicide had contact with at least one health service in the year prior to their death[4].

There is limited evidence of the effectiveness of interventions to prevent suicidal ideation, attempts and self-harm. Psychosocial and behavioural interventions that directly address suicidal ideation and behaviour have been found to be effective immediately post-treatment and long term[5]. Psychosocial interventions delivered in both in- and out-patient settings may also be effective in reducing future repetition of self-harm following a first episode[6–8]. Evidence suggests that Cognitive Behaviour Therapy (CBT)-informed approaches can lead to fewer participants repeating self-harm over time together with beneficial effects for secondary outcomes of depression, hopelessness, suicidal ideation and problem solving[8]. There is also some evidence for the effectiveness of safety planning-type interventions in suicide prevention[9]. Other therapeutic approaches have been shown to lead to less frequent, but no overall reduction, in the proportion of individuals engaging in self-harm at 6 or 12 months. However, none of these reviews systematically assessed the role of intervention duration, intensity, setting or practitioner[6–8].

There is some evidence that brief suicide prevention interventions are associated with reduced subsequent suicide attempts and increased follow-up care engagement[10]. A recent narrative synthesis of approaches used in national suicide prevention programmes included a meta-analysis of 12 eligible studies on the effectiveness of brief interventions and found only weakly supportive evidence of the effectiveness of brief interventions on repeated self-harm, suicide attempts, and suicide[11]. The review stressed the methodological limitations of current evidence and concluded that further suicide prevention evaluation studies are needed[11]. A review of international distress brief intervention research literature was undertaken to inform the development of Scotland's Distress Brief Intervention programme[6]. It found that despite the existence of international data exploring the effectiveness of brief interventions in reducing suicidal ideation and attempts and self-harm, intervention studies are scarce, small-scale and vary widely in format, intervention design, target population and outcome measure[6].

Conceptual framework

The conceptual framework for this study is grounded within the Integrated Motivational-Volitional (IMV) Model of Suicidal Behaviour[12]. The IMV model is based on the premise that factors associated with the emergence of suicidal thoughts (e.g., early life adversity, 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 model, volitional moderators (e.g., access to means, planning, impulsivity, past suicidal behaviour) govern the transition from suicidal ideation to behaviour. This is a dynamic process that for many is cyclical in nature, moving from suicidal thinking to attempt and back to thoughts over time, with the time between thoughts and action becoming less, reducing opportunity to intervene[12].

Intervention and study setting

To address the need to improve the response to adults (aged 18+) in distress identified in their Suicide Prevention and Mental Health strategies[13,14], the Scottish Government launched the Distress Brief Intervention (DBI) programme in 2016 (https://www.dbi.scot/). The aim of the DBI programme is to enable and improve inter-agency co-ordination and collaboration to deliver an effective response for people in distress to improve their experiences of support and their outcomes.

The DBI programme was tested and developed across Health Boards in four pilot sites in Scotland (Aberdeen, Inverness, Lanarkshire, and the Scottish Borders). A mixed-methods realist evaluation of DBI with adults (>=18 years) in the four pilot sites demonstrated that the intervention was feasible and acceptable to practitioners and to people receiving the service[6].

The DBI pilot programme brought together local NHS (primary care and emergency departments) and voluntary DBI provider partnerships, national agencies (Police Scotland, Scottish Ambulance Service, and NHS 24), voluntary sector mental health organisations and University of Glasgow with six delivery teams operating in four regions (Aberdeen, Borders, Inverness, and Lanarkshire). In 2019 DBI was extended to those aged 16 years and over and is on course to be embedded in each of Scotland's 31 Health and Social Care Partnership areas during 2024[15]. To enable Scotland-wide access for people in distress during the COVID-19 pandemic, in 2020 the NHS 24 Mental Health Hub was added as a referral route to DBI in all Health Board areas.

DBI comprises two levels. DBI Level 1 is provided by trained front-line staff (Primary Care, Police Scotland, Scottish Ambulance Service, Emergency Departments and NHS 24) who offer a compassionate response to individuals in distress and, where necessary, provide onward referral to a Level 2 service. DBI Level 2 is provided by trained voluntary sector practitioners. Individuals referred from Level 1 are

contacted by a DBI practitioner within 24 hours and offered up to 14 consecutive days of community-based, person-centred, solution-focussed support from a DBI practitioner. DBI Level 2 explores the nature and cause of an individual's distress and how it can be managed to prevent future distress. Service users can co-create a Distress Management Plan (DMaP) with their practitioner (a previous evaluation of DBI suggests many individuals were using their DMaP three months on from DBI)[6]. If appropriate, DBI Level 2 service users can be signposted to and/or receive support to engage with further community or statutory service support.

An evaluation of the implementation and impact of the DBI pilot programme found that pre-post measurements of distress (CORE-OM 5[16]) indicated that most participants' levels of distress reduced following DBI[6]. Qualitative evidence also indicated that without DBI, approximately 10% of study participants felt they would have gone on to die by suicide[6]. There is, therefore, early evidence that the DBI programme 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 and cycles of suicidal behaviour. This current 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.

While little is known about the impact of brief interventions on suicidal ideation, the DBI programme evaluation findings tentatively suggest that the DBI intervention could play a role in the prevention of suicidal behaviour[6]. 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.

The setting for this study is Scotland, the second largest country in the UK with a population of around 5.5 million. Nearly 96% of Scotland's population report their ethnicity as 'white'. Scotland has the highest suicide rate in the UK, with 762 probable suicides in 2022[2]. Rates of attempted suicide have risen among adults (aged over 16) in Scotland from 4% of Scottish adults in 2008/2009 to 7% in 2021/2022[17]. Rates of self-harm among adults have also increased over time in Scotland, from 2–3% in 2008/2009 to 10% in 2021/2022[17].

Between October 2022 and September 2023, the DBI programme received an average around 1500 referrals a month, 60% of which were female. Most Level 2 referrals are made by Level 1 trained staff in the NHS 24 MHH and in-hours primary care. Nearly 70% of referrals are for people living in Scotland's five most deprived deciles (according to the Scottish Index of Multiple Deprivation)[18]. DBI data from the year ending September 2023 indicates that the most common presenting problems are stress and anxiety (68% of referrals), depression and low mood (64%), suicidal thoughts (36%), self-harm thoughts or behaviours (7-9%), and suicidal behaviour (5%). The most reported contributory factors are relationship issues (41% of referrals), emotional wellbeing (29%), life coping issues (28%), employment issues (18%), and money worries (17%)[19].

Protocol

Patient and Public Involvement

The development of the DBI programme 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. Previous DBI service users, including those who had experienced suicidality, have reviewed the study design to establish how and when people with experience of DBI could effectively be involved in the study. This helped to refine the study's PPI plans and reduce 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 study design:

- Inclusion criteria for the survey 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.
- Creation of a PPI Study Advisory Group leader role from within the PPI group.

PPI is 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 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.

Study design

This is a mixed method evaluation which incorporates a combination of quantitative and qualitative measures of DBI impact and continuous improvement elements. This 36-month study combines: longitudinal surveys and in-depth interviews with individuals up to a year following their use of the DBI service; interviews with a qualitative comparator group; comparative analysis of nationally available health outcome data for a DBI service user group and retrospective comparator group; focus groups with providers involved in the delivery of DBI; and a survey of GPs to develop an

economic model of care pathways available to GPs to support people in distress and at risk of self-harm.

Research questions and objectives

The overall aim of this study is 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.

In line with the study aim, the research questions are:

1. Does DBI help people who present in crisis and distress with current or previous suicidal ideation, suicide attempts or self-harm achieve better outcomes in the immediate, short and longer term?
2. 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?
3. 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?
4. What aspects of the DBI programme contribute to these different outcomes, how and why? (e.g., 24hr response, intensity of intervention, problem solving strategies including the distress management plan (DMaP), onward referral/signposting to other services or support).
5. How does the length of the DBI Level 2 intervention impact on the above outcomes?
6. 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?
7. 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?
8. Is DBI Level 2 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?
9. What is the health care, social care and third sector resource use for DBI service users over the 12-month period following their DBI Level 2 intervention?
10. 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?

Primary and secondary outcomes

Primary outcomes are changes in suicidal ideation, suicidal behaviour and self-harm reduction in the immediate (1 month), short (3–4 months) and longer term (1 year).

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

Study governance

The study will be overseen by a steering group comprising representatives with academic expertise in complex health evaluations and economic evaluation, and representatives from services that act as DBI Level 1 providers (e.g., the Scottish Ambulance Service, Police Scotland, and NHS 24 MHH).

Data collection

DIMES is a mixed methods study that makes use of data from a variety of sources to address the research questions, as outlined in Figure 1.

Quantitative data collection from individuals accessing DBI

Quantitative data from individuals accessing DBI will be collected at up to five time points to explore whether DBI helps those who present in crisis and distress with current or previous suicidal ideation, suicide attempts or self-harm achieve better outcomes in the immediate, short and longer term and whether their outcomes differ for other DBI service users, and which aspects of the DBI intervention contribute to these different outcomes. Data will also be collected on health and social care use and third sector resource use to estimate the impact of DBI on service users care use (RQs 1, 2, 3, 4, 5 and 9).

The data will be collated from three sources: service user surveys, routine service delivery data collected by the DBI service and Public Health Scotland's Unscheduled Care Data Mart.

DBI service user surveys

Individuals accessing the DBI Level 2 service will be invited to complete four Level 2 DBI service user surveys. These surveys will be administered by DBI Level 2 staff (at the first and final DBI Level 2 sessions) and the ScotCen research team (3–4 months and 1 year) by email, text or paper.

The survey instruments include a combination of validated scales and bespoke closed questions as well as a small number of open questions to measure the following:

- Level of distress measured using the distress thermometer scale[20]
- Suicidal ideation, suicidal behaviour, and self-harm identifying first time/repeat disclosure
- Psychological distress as measured by the Clinical Outcomes in Routine Evaluation 10 (CORE-10) scale[21]
- Feelings of entrapment as measured by the Entrapment Scale-Short-Form (E-SF)[22]
- Attitudes to help-seeking as measured by the Self-Stigma of Seeking Help Scale (SSOSH)[23]

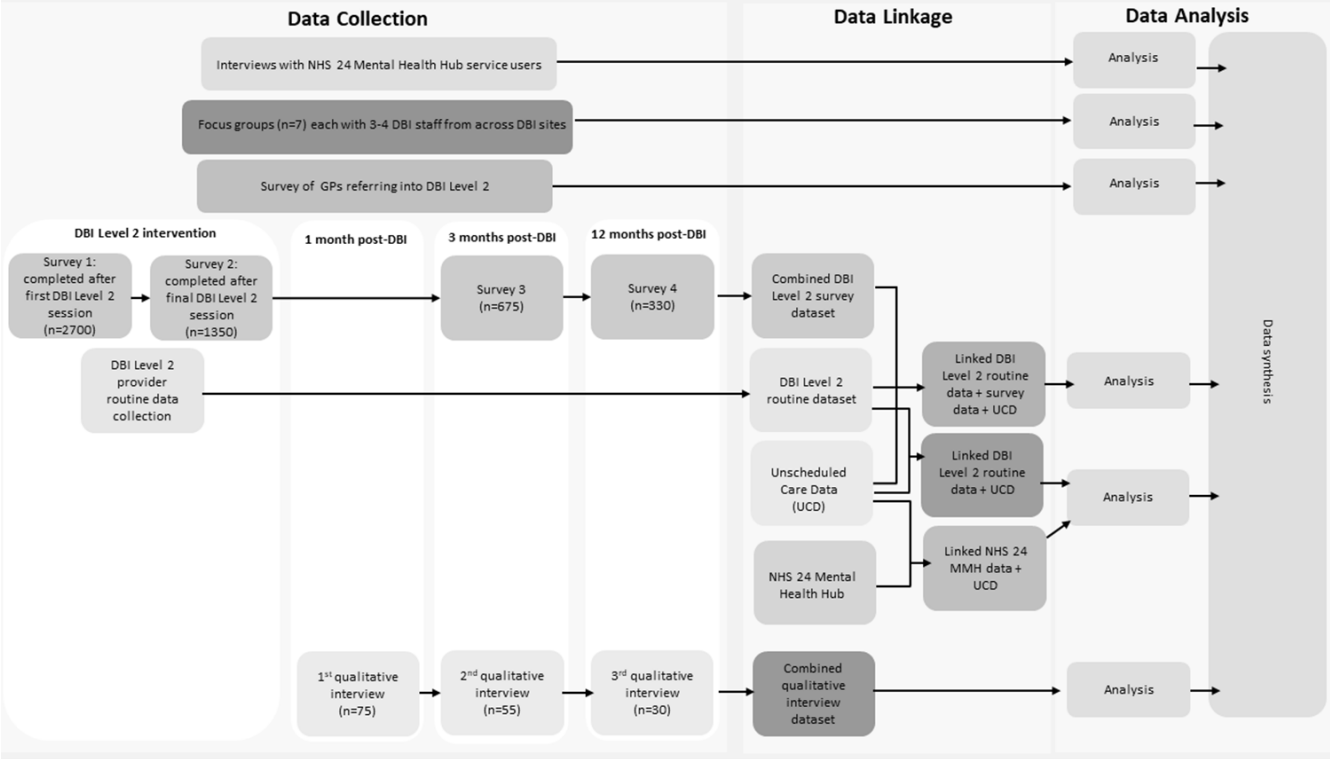

Figure 1. DIMES study data collection, linkage and analysis flow diagram.

- Recovery as measured by the Recovering Quality of Life scale (ReQoL-10)[24]
- Health related quality of life, measured using the EQ-5D-5L instrument[25]
- Health, social care and third sector resource use, measured using a resource use questionnaire designed specifically for the DIMES study
- Perceptions of which aspects of DBI, if any, that are most beneficial for above outcomes, including contact within 24 hours of referral
- Impact of other sources of support or life circumstances on above outcomes
- Whether further support from DBI would be beneficial, what form this might take and why.

Participants will receive a £10 high street shopping voucher as compensation on completion of each of the surveys.

DBI routine dataset

The DBI routine dataset comprises the following: DBI service user socio-demographic characteristics, service usage, including length of support, number of sessions and presenting problems.

Unscheduled Care Datamart

The Unscheduled Care Data Mart (UCD) is a collaboration between Public Health Scotland (PHS), NHS 24 and Scottish Ambulance Service (SAS). The data mart links data from NHS 24, Scottish Ambulance Service, Out of Hours Primary Care, Emergency Department, Acute, Mental Health and Deaths to show a patient journey for all those with a valid Community Health Index number.

The linkage of outcome data with service user characteristics and DBI intervention activity and unscheduled care use will facilitate analysis of service user sub-groups and intervention factors and to examine differences in unscheduled care use one year before and after DBI.

Individual level data linkage between the DIMES participant survey dataset, the routine dataset collected by DBI and the Unscheduled Care Datamart (UCD) will be undertaken in the Scottish National Safe Haven.

Recruitment and sampling: 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 by trained DBI Level 2 staff. DBI service users under the age of 16 or for whom participation in the study is not deemed appropriate by DBI staff, depending on individual circumstances, will be excluded. Based on the previous evaluation (pre-Covid) the estimated Level 2 DBI service users' survey sample size is a maximum of 2,700 respondents with anticipated attrition at each time point (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).

Consent: A participant information sheet and privacy statement containing full study details will be provided to participants by DBI L2 staff. Consent to take part in the study and to link data to both the DBI dataset and UCD data is collected and recorded at the start of the first survey.

***Analysis*:** Data analysis of quantitative data collected via surveys, routine data and unscheduled care will include descriptive statistics and crosstabulation analysis with logistic regression if appropriate to track and compare changes in outcomes at the different time points up to one-year post-DBI. Demographic, referral source and presenting problem characteristics of survey respondents and non-respondents will be compared to assess the representativeness of the survey sample and whether any weighting adjustments are required.

Qualitative interviews with individuals accessing DBI and a qualitative comparator group

To gain deeper insights into the outcomes for those who access DBI with current or previous suicidal and/or self-harm ideation or attempts and whether, how and why DBI contributes to these different outcomes (RQs 1, 2, 4 and 5), qualitative interviews will be undertaken with a sample of those who access DBI and a qualitative comparator group.

Qualitative interviews with a sample of DBI service user participants with a history of suicidal risk based on quantitative survey responses will be undertaken at 1 month, 3–4 months and 1 year following DBI L2 intervention. Based on quantitative survey responses, potentially eligible participants will be contacted by the research team to conduct a safe screening process to further assess their eligibility to take part in interviews. The safe screening follows a standard protocol, developed by the Suicidal Behaviour Research Laboratory and has been used in many previous studies with suicidal and vulnerable groups. The safe screening protocol includes:

- Introducing and providing 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 an initial Safe Screening telephone call, a suicide risk assessment will be carried out. A risk mitigation strategy proportionate to the level of risk will be made; all participants will be encouraged to develop or maintain a safety plan and provided with a sources of support sheet. During the screening call, eligibility criteria are checked. Risk assessment and mitigation protocols are followed prior to and following any subsequent interview calls.

The eligibility criteria for inclusion in the interviews are:

- experienced suicidal thoughts, behaviour or self-harm at any time in the last 12 months
- able to provide consent
- a level of literacy that is sufficient to complete relevant assessment measures, engage with telephone contact and support, or participate in interviews
- able to provide contact details

The semi-structured interviews will be conducted face to face, by video or telephone and last for approximately one hour. Interview guides will be used to explore:

- The individual's DBI story from referral to exit and any ongoing impacts
- Perceptions of what aspects of DBI support, if any, were most beneficial in helping with study-specific outcomes as well as contributory outcomes e.g. financial support.
- Impact of other informal and formal sources of support (including services sign-posted by DBI) and changes in life circumstances on above outcomes
- 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
- Ways in which DBI could be improved

To provide a comparator with those accessing DBI, qualitative insights from users of the NHS 24 MHH between October 2019 and March 2020 will be gathered via Scottish lived experience networks. This group provides a comparison with DBI as the NHS 24 MHH was the most similar national service available for individuals experiencing distress prior to the roll out of DBI via NHS 24. Similar screening, risk assessment and mitigation protocols used with DBI service user interview participants will be employed for this group of participants. Unlike DBI service user interviews, those conducted with the comparator sample will only be conducted once.

The interviews will cover the individual's story from referral to exit from the NHS 24 MHH and will address a subset of issues explored with the DBI service user participants focused instead on experiences of NHS 24 MHH. Participants will receive a £25 thank you voucher as compensation for their time following each interview.

Recruitment and sampling

Individuals accessing DBI: Evaluation participants aged 16 or over who have agreed in their second survey (issued at their final DBI L2 session) to be contacted for interview, and who have experienced suicidal thoughts, behaviour or self-harm at any time in the last 12 months are eligible. Full

eligibility criteria are listed above. A maximum 75 people will be recruited.

Qualitative comparator group: Individuals who contacted the NHS 24 MHH between Oct 2019 and March 2020 for reasons of mental health or distress, who have experienced suicidal thoughts, behaviour or self-harm and who have been assessed as eligible during the Safe Screening process will be included. The sample of 15 interviews is based on the premise that the open invitation to participate through mental health lived experience networks will yield small numbers, however 15 interviews should be sufficient to provide the insights required for this study.

Consent: A participant information sheet and privacy statement containing full study details will be provided to participants in advance of their interview and verbal consent will be collected and recorded.

Analysis: Qualitative interviews will be summarised, charted and coded using QSR NVivo 12 and analysed with reference to techniques of framework analysis[26]. We will explore any differences or similarities in the views of the DBI and qualitative comparator participants to assess any perceived impact of the DBI programme, while paying attention to other contextual influences.

Comparator group data collection

A comparator group of those who accessed NHS24 for mental health distress reasons prior to the introduction of DBI will be identified. The use of unscheduled care (as determined by UCD data) 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 different for DBI service users (RQ 8).

Following approval from the NHS Public Benefits and Privacy Panel (PBPP), people who received DBI between Jan 2022 and Jan 2023 will be identified through the DBI database held by PHS which will be linked to the UCD by eDRIS. As noted above, a retrospective comparator group will be identified using the UCD to undertake a comparison with the DBI service user group. We will select the comparator group from those accessing the NHS 24 Mental Health Hub (MHH) who could not be referred to DBI because they accessed the MHH prior to DBI's national roll out throughout Scotland via NHS 24. We will request UCD records from 2018–2021 for people who contacted NHS 24 in October 2019 to March 2020 for mental health reasons. The NHS 24 data indicates whether a call went to the NHS 24 MHH. A call related to mental health will be used as the comparator event. The comparator event(s) is/are a good proxy for presenting to unscheduled care experiencing mental distress.

Information will be collected on:

- Service use outcomes in the year before and the year after the index call.
- 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.
- 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.

Sampling: UCD records for 2018–2021 for people who contacted NHS 24 in October 2019 to March 2020 for mental health reasons will be requested. 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.

Analysis: 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. 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.

The comparative analysis 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. This analysis will include adjustment for potentially confounding sociodemographic variables. Secondary analyses and likely zero inflation will be assessed.

Focus Groups with DBI staff

To explore from the DBI provider perspective ways in which DBI might improve its contribution to positive outcomes for people who present with suicidal ideation/suicidal behaviour/self-harm (RQs 6 and 7), and whether those accessing DBI with suicidal ideation/suicidal behaviour/self-harm would benefit from a 'DBI Level 3' to provide follow-up over a longer period and how this might be implemented.

Seven focus groups will be held with DBI provider staff representatives. Six focus groups will be held across DBI provider sites in Scotland with local DBI Level 2 staff members, DBI Level 1 service representatives (police, ambulance and A&E) and management and one will be held with representatives of the DBI Central Team leadership and DBI Programme Board. These focus group discussions will explore staff and programme leadership and board perceptions of:

- Impact(s) the 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 DBI contribute most to the above and why
- Contributing factors and barriers to their ability to support people with the above
- Unintended consequences of DBI
- Perceptions of whether and how follow-up DBI support for people with above problems would be beneficial
- Impact of Covid-19 on the above

Recruitment and Sampling: Those working in or with DBI Level 1 and Level 2 would be eligible to take part in the focus groups as well as DBI local provider management, DBI Central team leadership and DBI Programme Board members. Sample size=42 – 56 (6–8 per focus group), one focus group per site.

Consent: Full study details will be provided to participants in advance of their interview and verbal consent will be collected and recorded.

Analysis: Focus groups will be analysed in NVivo using a framework matrix to explore themes across the data[27].

Economic modelling of care pathways

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. 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 (RQ 10). 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.

A survey will be undertaken with a sample of up to 20 GPs in NHS Boards who have been trained to provide Level 1 DBI to determine the typical care pathway for individuals in distress and at risk of self-harm. 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[6]. 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.

Analysis: Data from the GP survey will be used to model typical care pathways options, including the role of DBI Level 2 in the pathway. Resource use and costs of pathways will be presented. Units of each item for all care pathways and for participant resource use will be collated and presented. These pathways will not consider individual level resource use.

Data synthesis

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 a study advisory group 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.

Ethics and dissemination

Ethical approval for this study has been obtained from NHS West of Scotland Research Ethics Service (REC reference: 22/WS/0114; approved 05.10.2022).

A final study report will be published in *Health and Social Care Delivery Research* as part of the NIHR Journals Library. The study team will publish journal articles and UK and international conference papers.

The study findings will also feed into the DBI continuous improvement programme. Interim findings and study progress will be shared with DBI service providers, users, and other stakeholders via presentations at two DBI Gatherings (large interdisciplinary and interagency networking meetings, including government and service user organisations to communicate and build DBI programme cohesion) during the study, at two study seminars of up to 20 DBI staff and stakeholders, and at a final learning event with up to 60 stakeholders.

Conclusion

Informed by lived experience and the integrated motivational-volitional model, this study will draw on a wide range of quantitative and qualitative methods and data sources to understand whether and how DBI improves outcomes for those presenting with self-harm and/or suicidal ideation and/or behaviours. Those accessing DBI with these experiences will be asked to provide survey and interview data for up to a year following DBI support on their experience, outcomes and service use. A retrospective comparator group will be used to assess the impact of DBI on unscheduled care use for a year following DBI support. DBI staff perceptions will be gathered via focus groups and GPs will be asked to provide data on care pathways to support people in distress with suicidal or self-harm thoughts or behaviours and the resource use associated with this. These data will be synthesised to inform an impact and economic analysis.

This study will directly inform the DBI continuous improvement programme. We will use the co-applicants' organisational 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. This will allow us to reach a wide range of practitioner, service user and research audiences as well as broader communities of interest, including the public and key international networks such as the International Initiative for Mental Health Leadership.

The key impacts of this study should include improvement of the current DBI intervention model in relation to supporting those who have self-harmed, had suicidal thoughts or behaviours. Such improvements should result in better outcomes for people who use DBI as a source of support. The study will further raise awareness among policy makers, service providers and the public of the need to provide appropriate and timely compassionate support to those who have self-harmed, had suicidal thoughts and behaviour. Additionally, it will also increase the acceptability and validity of talking about and addressing the problem of suicide head-on through safe research focussed methods and outcomes that matter to those who use crisis/mental health services. If successful, this project would be a useful example of how to involve people in distress directly in the quality improvement process, with benefits for all. It would also add to the self-harm and suicide prevention evidence base and improve our understanding of the cycle of self-harm and suicidal behaviour.

Challenges

The study was designed before Covid-19 and began when the final social distancing measures were being lifted. Lockdown had a knock-on effect on DBI in terms of a switch in the mode of service delivery to remote (at the time expected to be temporary); rapid expansion of the service to meet growing demand as the stresses of Covid-19 affected increasing numbers of people; more people presenting to frontline services with higher severity of distress than pre-Covid; and DBI workforce challenges. While these circumstances highlighted the vital need for this study to go ahead, they also presented significant challenges for the study team to ensure ethical and safe support for DBI staff, as well challenges for the recruitment of people presenting to DBI in distress in an unscheduled way.

Limitations

It was not possible for scientific, practical and ethical reasons to conduct a randomised controlled study which is a limitation of this study. Prior to the introduction of DBI, there was no standard response or care pathway for people who were in distress or suicidal, but many would present to ambulance, police or A&E, meaning that there were no existing approaches in place which could provide an effective comparison to DBI. However, our mixed-methods design which includes robust qualitative impact combined with QED elements brings multiple benefits. For example, by using different approaches to determining impact, we can analyse not just whether intended outcomes were realised (or not) but how and why, and such analyses will support the interpretation of the quantitative findings.

DBI makes use of a wide network of voluntary and statutory organisations to sign-post DBI service users to but do not follow-up with these services. It would not be possible to comprehensively track post-DBI service use of these services and therefore the study will be reliant on DBI routine data on referrals made and self-report by service users of uptake and perceived outcome.

Strengths

This study is focused on generating high-quality and evidence-based knowledge about the impact of brief interventions on those experiencing suicide and/or self-harm thoughts and/or behaviours through the study of the highly innovative and unique DBI Programme. The study design, like DBI itself, is grounded in lived experience and takes a real-world approach to understanding whether and how DBI makes a difference, using a range of methods. It considers whether, how and why DBI works for people in distress with different needs and circumstances. The collection of longitudinal data over a 1-year period and analysis of in-depth qualitative impact evidence is a key strength of this study, supporting its aim to understand the mechanisms of change involved in DBI. Another strength is our ability to explore the influence of contextual factors on the delivery and potential effectiveness of DBI. To maximise impact, utilisation of interim and end of study findings will be encouraged through participatory learning events with service users, DBI L1 and L2 staff, national and local policy makers and academics.

Data (and software) availability

No data are associated with this article.

Acknowledgments

We would like to thank the Distress Brief Intervention national team and provider teams for supporting this evaluation.

References

1. World Health Organization: **Suicide prevention**. 2024.
Reference Source
2. National Records of Scotland: **Probable suicides**. 2023.
Reference Source
3. Health Scotland: **Social isolation and loneliness in Scotland: a review of prevalence and trends**. 2018.
Reference Source
4. Public Health Scotland: **Scottish suicide information database a report from the scottish suicide information database**. 2023.
Reference Source
5. Scottish Government Health Analytical Services: **Distress brief interventions: rationale and evidence**. Scottish Government; 2015.
Reference Source
6. Duncan E, McLean J, Calveley E, *et al.*: **Evaluation of distress brief intervention programme**. Scottish Government; 2022.
Reference Source
7. Hawton K, Witt KG, Salisbury TLT, *et al.*: **Psychosocial interventions following self-harm in adults: a systematic review and meta-analysis.** *Lancet Psychiatry.* 2016; **3**(8): 740–750.
PubMed Abstract | **Publisher Full Text**
8. Hetrick SE, Robinson J, Spittal MJ, *et al.*: **Effective psychological and psychosocial approaches to reduce repetition of self-harm: a systematic review, meta-analysis and meta-regression.** *BMJ Open.* 2016; **6**(9): e011024.
PubMed Abstract | **Publisher Full Text** | **Free Full Text**
9. Nuij C, van Ballegooijen W, de Beurs D, *et al.*: **Safety planning-type interventions for suicide prevention: meta-analysis.** *Br J Psychiatry.* 2021; **219**(2): 419–426.
PubMed Abstract | **Publisher Full Text**
10. Doupnik SK, Rudd B, Schmutte T, *et al.*: **Association of suicide prevention interventions with subsequent suicide attempts, linkage to follow-up care, and depression symptoms for acute care settings: a systematic review and meta-analysis.** *JAMA Psychiatry.* 2020; **77**(10): 1021–1030.
PubMed Abstract | **Publisher Full Text** | **Free Full Text**
11. Platt S, Niederkrotenhaler T: **Suicide prevention programs: evidence base and best practice.** *Crisis.* 2020; **41**(Suppl 1): S99–S124.
PubMed Abstract | **Publisher Full Text**
12. O'Connor RC, Kirtley OJ: **The integrated motivational–volitional model of suicidal behaviour.** *Philos Trans R Soc B Biol Sci.* 2018; **373**(1754): 20170268.
PubMed Abstract | **Publisher Full Text** | **Free Full Text**
13. Scottish Government: **Scottish government mental health strategy: 2017-2027**. 2017.
Reference Source
14. Scottish Government: **Scotland's suicide prevention action plan: life matters**. 2018.
Reference Source
15. Health and Social Care Scotland: **Health and social care partnerships**. Published 2023; Accessed March 11, 2024.
Reference Source
16. Connell J, Barkham M, Stiles WB, *et al.*: **Distribution of CORE–OM scores in a general population, clinical cut-off points and comparison with the CIS–R.** *Br J Psychiatry.* 2007; **190**(1): 69–74.
PubMed Abstract | **Publisher Full Text**
17. Scottish Government: **The Scottish health survey 2022 – volume 1: main report**. 2023.
Reference Source
18. Public Health Scotland: **Scottish Index of Multiple Deprivation (SIMD)**. 2024.
Reference Source
19. Distress Brief Intervention: **DBI infographic report: all areas and sources combined. reporting period:: up to september 2023**. 2023.
20. Cutillo A, O'Hea E, Person S, *et al.*: **The distress thermometer: cutoff points and clinical use.** *Oncol Nurs Forum.* 2017; **44**(3): 329–336.
PubMed Abstract | **Publisher Full Text** | **Free Full Text**
21. Barkham M, Bewick B, Mullin T, *et al.*: **The CORE-10: a short measure of psychological distress for routine use in the psychological therapies.** *Couns Psychother Res.* 2013; **13**(1): 3–13.
Publisher Full Text
22. De Beurs D, Cleare S, Wetherall K, *et al.*: **Entrapment and suicide risk: the development of the 4-item Entrapment Scale Short-Form (E-SF).** *Psychiatry Res.* 2020; **284**: 112765.
PubMed Abstract | **Publisher Full Text**
23. Vogel DL, Wade NG, Haake S: **Measuring the self-stigma associated with seeking psychological help.** *J Couns Psychol.* 2006; **53**(3): 325–337.
Publisher Full Text
24. Keetharuth AD, Brazier J, Connell J, *et al.*: **Recovering Quality of Life (ReQoL): a new generic self-reported outcome measure for use with people experiencing mental health difficulties.** *Br J Psychiatry.* 2018; **212**(1): 42–49.
PubMed Abstract | **Publisher Full Text** | **Free Full Text**
25. Herdman M, Gudex C, Lloyd A, *et al.*: **Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L).** *Qual Life Res.* 2011; **20**(10): 1727–1736.
PubMed Abstract | **Publisher Full Text** | **Free Full Text**
26. Gale NK, Heath G, Cameron E, *et al.*: **Using the framework method for the analysis of qualitative data in multi-disciplinary health research.** *BMC Med Res Methodol.* 2013; **13**(1): 117.
PubMed Abstract | **Publisher Full Text** | **Free Full Text**
27. NVivo: **Computer assisted software for qualitative analysis**. Published online 2022.

Open Peer Review

Current Peer Review Status: ? ✗ ?

Version 1

Reviewer Report 17 September 2024

https://doi.org/10.3310/nihropenres.14754.r32701

?

A Jess Williams
King's College London, London, UK

The protocol outlines a new approach to managing suicide risk by referral to a distress brief intervention (DBI). The intervention's first level is to provide a compassionate response to those presenting in distress followed by the second level which is ongoing support for 2-weeks, received within 24hours of presentation. The intervention has been trailed in Scotland, and this next study fills a clear evidence gap considering how effective and acceptable this intervention will be. A variety of methods will be used to triangulate the perceived impact of DBI, which is a strength of the protocol. A few recommendations are included to enhance the clarity of the manuscript.

Introduction:
Paragraph 3: The first two sentences appear contradictory, would consider revision for clarity. – *"There is limited evidence of the effectiveness of interventions to prevent suicidal ideation, attempts and self-harm. Psychosocial and behavioural interventions that directly address suicidal ideation and behaviour have been found to be effective immediately post-treatment and long term5"*
Intervention:
DBI Level 2: Is all support based in-person or are digital resources used as well?
A brief description of the Distress Management Plan would be helpful and an outline of other components to gain a clearer understanding of the intervention.
Is there any information available about how much participants engaged with DBI Level 2? E.g. x% participants attended all 14-days' worth of DBI supports? It would be interesting to understand who DBI may not work for initially.
Can people be referred and utilise DBI more than once? How might this effect outcomes?
I would like to see how the DBI links to the IMV model, as currently this relies on a level of suicide expertise from the reader.
Patient and public involvement:
How many people were involved with the development of the programme? Was there overlap with those who reviewed the study design? I like that PPI was used at this stage to create an ongoing PPI plan to support involvement!
Research questions:
10: *"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?" Is this exploring what other care pathways exist such that authors can compare with DBI later? If GPs are asked to refer patients to DBI, couldn't this lead to a bias? Maybe rewording would make this clearer.
Methods: Quantitative:
Could authors clarify if *"Quantitative data from individuals accessing DBI will be collected at up to five time points"* means from all individuals accessing DBI at the time of data collection, or from an individual accessing DBI up to 5 times?
How long does the DBI service user survey take?
Figure 1 is really helpful!
Methods: Qualitative:
The comparator group accessed service 2019-2020, it's likely that there is a difference in the service provided now. It would be good to try for an updated comparison, considering only 15 interviews are being sought.

Is the rationale for, and objectives of, the study clearly described?
Yes

Is the study design appropriate for the research question?
Yes

Are sufficient details of the methods provided to allow replication by others?
Partly

Are the datasets clearly presented in a useable and accessible format?
Yes

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: self-harm, suicide, interventions

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.

Reviewer Report 06 September 2024

https://doi.org/10.3310/nihropenres.14754.r32453

Gerd Wagner
Jena Center for Mental Health, Jena University Hospital, Jena, Germany

This is a very important approach to providing timely care for people in crisis, especially suicidal

crises, in order to reduce the likelihood of self-harm. However, I have strong doubts as to whether the study with the described design has the statistic power to answer the targeted question.
First of all, this is not a randomized controlled trial, which clearly limits the significance of the intervention's effectiveness.
Secondly, the primary outcomes are defined as changes in suicidal ideation, suicidal behaviour and self-harm reduction in the immediate (1 month), short (3–4 months) and longer term (1 year). It is not clear how the authors intend to compare the outcome variables and whether the significance is sufficient to detect changes. The power analysis is missing in this study. It is likely that suicidal ideation, as a metric variable, changes (although the study design now leaves it unclear whether this is due to the intervention), but how do the authors intend to capture changes in suicidal behavior?
The authors state that DBI data from the year ending September 2023 indicates that the most common presenting problems are stress and anxiety (68% of referrals), depression and low mood (64%), suicidal thoughts (36%), self-harm thoughts or behaviours (7–9%), and suicidal behaviour (5%). Thus, around 75 suicide attemters were seen. I doubt that the statistical power is sufficient to see any effects, furthermore a control condition is absolutely necessary to be able to make any statement at all about the effect of the intervention on the number of suicide attempts or NSSIs in the follow-up period.
Further comments:
"There is limited evidence of the effectiveness of interventions to prevent suicidal ideation, attempts and self-harm." please see the meta-analysis (Ref 1)
It not clear how the IMV model is integrated into the DBI.
"DBI Level 2 explores the nature and cause of an individual’s distress and how it can be managed to prevent future distress." Please explain in more detail how it is done?
"Voluntary sector practitioners" What training do these people have?

References

1. Sobanski T, Josfeld S, Peikert G, Wagner G: Psychotherapeutic interventions for the prevention of suicide re-attempts: a systematic review.*Psychol Med*. 2021; **51** (15): 2525-2540 PubMed Abstract | Publisher Full Text

Is the rationale for, and objectives of, the study clearly described?

Partly

Is the study design appropriate for the research question?

Partly

Are sufficient details of the methods provided to allow replication by others?

Partly

Are the datasets clearly presented in a useable and accessible format?

Not applicable

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Suicodology, Psychotherapeutic treatments of suicidal behavior, Neurobiological research on suicidal behavior and depression

I confirm that I have read this submission and believe that I have an appropriate level of expertise to state that I do not consider it to be of an acceptable scientific standard, for reasons outlined above.

Reviewer Report 10 July 2024

https://doi.org/10.3310/nihropenres.14754.r32044

?

Alexandra Pitman
University College London, UCL Division of Psychiatry, London, UK

Overall comments

The DBI is a promising intervention in addressing suicidality and self-harm but there is a clear evidence gap to address in terms of effectiveness and acceptability. This mixed methods evaluation study takes a comprehensive approach, involving people with lived experience, and the findings will be of great interest to the clinical and policy community as well as to those with experiences of poor care when in crisis.

Abstract

There is some anthropomorphism of DBI that doesn't sound right eg "DBI promises to make contact within 24 hours" – whereas it would be better to say "the DBI service promises to make contact within 24 hours".

Plain language summary
The phrase "We collect information in several ways, including:" should indicate "For the evaluation of the DBI service we will collect information in several ways, including," to be clear that this is for the evaluation of DBI and not as part of routine DBI record keeping, as it was vague to the lay reader.
Later on it is stated "DBI data from the year ending September 2023" and it would be important to be clear in the Introduction about the process (and content) of routine data collection within DBI, especially as later on it is stated that routine service delivery data collected by the DBI service will be analysed. The nature of the variables becomes clear much later on under measures.

Introduction

In the following sentences it would be good to clarify "none of the studies in these reviews" and to add citations to the first sentence.
Other therapeutic approaches have been shown to lead to less frequent, but no overall reduction, in the proportion of individuals engaging in self-harm at 6 or 12 months. However, none of these reviews systematically assessed the role of intervention duration, intensity, setting or practitioner[6–8]

. However, none of these reviews systematically assessed the role of intervention duration, intensity, setting or practitioner[6–8].

It is mentioned that:
A review of international distress brief intervention research literature was undertaken to inform the development of Scotland's Distress Brief Intervention programme.
However, the findings of the review regarding effectiveness are not actually stated.

Conceptual framework

Re the IMV, it is mentioned that "This is a dynamic process that for many is cyclical in nature, moving from suicidal thinking to attempt and back to thoughts over time, with the time between thoughts and action becoming less, reducing opportunity to intervene."
It could be clearer whether this temporal aspect (a reduced period of time for each successive cycle) of the theory has empirical support or not.

Intervention

It is mentioned that: "An evaluation of the implementation and impact of the DBI pilot programme found that pre-post measurements of distress (CORE-OM 5[16]) indicated that most participants' levels of distress reduced following DBI[6]." It would be important to add whether this was a significant reduction.

Research questions

3 - 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? – would be good to state that this latter group include those presenting with stress and anxiety (68% of referrals) and depression and low mood (64%) and other non-suicidal/SH reasons.

10. 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? I would assume that as DBI is well established they would refer for DBI, so I was not clear what aspect of care this would be picking up. Earlier on the plan is stated as "A survey of General Practitioners and a review of existing literature will be used to model typical care pathways for individuals in distress and at risk of self-harm." I was not clear what this existing literature was, and whether it would reflect the reality of what is currently happening.

Methods

The DBI service user surveys will be by email, text or paper – would they not be on a survey website with a paper version? Email/text sounds very unwieldy.

In the list of measures, no specific measure is stated for capturing suicidal ideation, suicidal behaviour, and self-harm (identifying first time/repeat disclosure).

Exclusion of those "for whom participation in the study is not deemed appropriate by DBI staff, depending on individual circumstances" needs explaining, so we know who will be excluded and

why.

It would be good to clarify throughout the methods which aspects relate to which RQ, as this happens later on but not throughout.

The longitudinal qualitative research design is a strength, although it would be good to state it explicitly as such in that section of the methods. The comparator group will only be interviewed once, recalling events prior to COVID and this is a weakness. Other options would be interviewing people in other devolved nations without access to DBI, but these have their own issues. It would be worth noting that the findings of the analysis will be interpreted in the context of likely recall bias in the comparator group.

It is stated that “Secondary analyses and likely zero inflation will be assessed” but this sounds quite exploratory – will analysis plans be uploaded to OSF or equivalent?
For the economic evaluation the plans are quite vague - “Resource use and costs of pathways will be presented. Units of each item for all care pathways and for participant resource use will be collated and presented. These pathways will not consider individual level resource use”. It is not clear if there is a plan to compare care pathways for individuals in distress and at risk of self-harm who use and do not use DBI.

Is the rationale for, and objectives of, the study clearly described?

Yes

Is the study design appropriate for the research question?

Yes

Are sufficient details of the methods provided to allow replication by others?

Partly

Are the datasets clearly presented in a useable and accessible format?

Yes

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: suicide; self-harm

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.