Conducting research in crisis helpline settings: common challenges and proposed solutions

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Suicide is a significant global public health concern, accounting for over 700,000 annual deaths worldwide (World Health Organisation [WHO], 2021). The tragedy of suicide results in lost opportunities for individuals to contribute to their community, work, and to love and be loved within their families, communities and friendship networks. Suicide has far reaching consequences, with those who have attempted suicide or are bereaved by suicide at higher risk of social and mental health problems, and of future suicidal behaviour (Bostwick et al., 2016; Goldmen-Mellor et al., 2014; Molina et al., 2019). In line with this need, many governments globally now recognise evidence-based suicide prevention as a national priority (WHO, 2014).

Telephone crisis helplines are an important part of suicide prevention systems, with most countries having at least one service (WHO, 2018). Crisis helplines provide immediate and anonymous support to people in distress or who are unable to cope with difficulties in their lives (WHO, 2018), and overcome a range of barriers to accessing face-to-face services by offering support regardless of time of day or geographical location. These qualities afforded by helplines may help to overcome common attitudinal barriers to seeking out mental health care and provide the opportunity for support to those who may not otherwise engage (WHO, 2018).

These distinguishing features of helplines combine to make them a heavily utilised form of mental health support. For example, Lifeline Australia responds to up to 3,000 calls

per day (Lifeline, 2021), and Samaritans in the UK respond to over 10,000 calls per day (Samaritans, 2021). It is estimated that between 25-60% of such calls relate to suicidal thoughts or feelings (O'Riordan et al., 2021; Samaritans, 2021).

Despite their frequent utilisation, evidence for the efficacy of crisis helplines is varied due to ethical and methodological challenges conducting rigorous research. To underpin their status internationally as a standard, scalable service for supporting people in crisis, there is opportunity to more deeply understand outcomes that can be achieved by crisis helplines. Whilst the pressing need to tackle challenges around conducting research at crisis helplines has been recognised (Hoffberg et al., 2020; Mathieu et al., 2021), little has been done to develop practical solutions. In this editorial, we discuss the ethical and practical barriers to conducting research in crisis helpline settings, focusing on the conduct of randomised controlled trials (RCTs) with the aim of offering potential solutions to common methodological challenges.

Ethical and practical challenges in crisis helpline research

Ethical and practical challenges in conducting suicide research are well cited. Key issues raised by researchers and ethics committees include the potential for research with suicidal populations to cause harm to participants, the capacity of individuals at higher risk for suicidality to provide informed consent, and concerns around researcher liability (Bailey et al., 2020; Hom et al., 2016). Individuals deemed too at-risk are often excluded from research to mitigate the possibility of increased distress. Consequently, interventions aimed at reducing suicide risk are typically not tested on those in acute need of support, creating related gaps in the literature around safe and effective suicide prevention (Bailey et al., 2020).

Despite these challenges, for the last 15 years researchers and stakeholders in suicide prevention have emphasised the need for rigorous intervention studies to be prioritised over

epidemiological studies (Reifels et al., 2018). While researchers and ethics committee members alike have previously noted difficulties in developing and approving suicide research protocols (Lakeman & Fitzgerald, 2009a, 2009b), ethics committee members have recently expressed an eagerness to support rigorous and safe suicide research applications (Barnard et al., 2021). Suicide-related studies need to demonstrate research merit, researcher expertise in suicide protocols, and adequate strategies to mitigate risks (Barnard et al., 2021).

Noting the fundamental importance of ethical considerations, the crisis helpline context offers a unique opportunity to evaluate suicide prevention interventions. Crisis helplines provide access to crisis support for people living with suicidality, rendering this context one of the most appropriate settings for assessing the efficacy of suicide prevention interventions with the very population most likely to benefit from them. With that in mind, crisis helpline research protocols that balance the ethical concerns of researchers and committees, extending research opportunities to include those that will benefit most, must be developed.

Previous research in crisis line settings

Whilst there is scope to extend research, innovative approaches to conducting research in crisis helplines over the last two decades have much improved understanding of their efficacy. Notable methodologies include analysis of taped calls (King et al., 2003), silent monitoring of calls (Mishara et al., 2007a, 2007b; Ramchand et al., 2016), enlisting crisis supporters to complete reports following calls (Gould et al., 2016), and assessments conducted by crisis supporters at the beginning and end of calls to assess short-term outcomes (Tyson et al., 2016; Gould et al., 2007; Kalafat et al., 2007).

Whilst such developments offer a range of opportunities to better understand the impact of crisis helplines a lack of consistency in outcome measurement approaches has

proved a limitation. A recent systematic review of crisis helplines identified no common definitions or standardised measures for caller outcomes across studies, with various outcomes measures utilised including mood (e.g. Profile of Mood States), distress (e.g. K-10), suicidality (e.g. Suicide Risk Status), and satisfaction with services (Mazzer et al., 2020). Further, many methodologies employ third parties (e.g. crisis supporters, silent monitors) to collect data as a proxy for first hand caller perspectives, due to difficulty implementing self-report measures. Despite conclusions of preliminary support for crisis helpline efficacy (Hoffberg et al., 2020), the variability of measurement and lack of self-report data is a limitation.

The need for consistent outcome measurement is coupled with an understanding of suicide that recognises the fluctuating state of suicidality that many people live with over time. Historical 'binary' perspectives on suicidality (present/absence) have been under scrutiny in recent years, as evidence mounts that the individual experience of suicidality is more complex (Maple et al., 2019; Webb, 2010). Emerging qualitative research shows that a suicide attempt, no matter how distal, continues to impact a person's life (Maple et al, 2019). This suggests that support for those who have attempted suicide might need to focus on living alongside and finding new meaning after the suicide attempt, as opposed to "getting over it" and returning to life as it was beforehand (Maple et al., 2019).

Emergent crisis helpline research also identifies that suicidal callers contact crisis helplines with diverse needs – with some callers uninterested in, unable or unwilling to disclose their thoughts of suicide. One study of callers to a telephone helpline found that up to 12% of those classified as non-suicidal at the time of their initial call reported subsequent thoughts of suicide at follow up (Gould et al., 2007). Further, a retrospective study of callers to an Australian crisis helpline found that callers who identified suicidality as a reason for

contact reported other more complex reasons for their call than non-suicidality related callers (O'Riordan et al., 2021).

Consistent with these findings, measuring the presence or absence of suicidality as an outcome is not the goalpost. Instead, the field is moving to acceptance of a broader definition of suicide prevention success regarding interventions around suicidality. Helping people effectively 'live with' transient or chronic suicidality may also be a positive outcome if they can live meaningfully, offering potential opportunity to reduce suicidal behaviours. Expected outcomes of crisis helplines must accomodate this evolving understanding.

In sum, we echo others (Mathieu et al., 2021; Mazzer et al., 2021) in calling for an increase in consistency of outcome measurement tools that are atuned to the context and role of crisis helplines. Further, we contend that outcome measurement must consider evolving understandings of suicidality as a fluctuating state. While efforts have been made to better understand crisis line efficacy, the lack of controlled studies presents a significant gap in current knowledge, and significant opportunity for further research.

RCTs – what are the challenges in the crisis helpline settings, and how might we overcome them?

Implementation of RCTs is particularly challenging in the helpline context. Although systematic reviews of the efficacy of helplines contend that RCTs are an invaluable tool for furthering our knowledge of intervention impacts (Hoffberg et al., 2020; Mathieu et al., 2021), only one has been conducted to date in this setting (see Gould et al., 2013). In this study, Applied Suicide Intervention Skills Training (ASIST) was evaluated using blinded silent monitoring of calls. Callers who received support from ASIST-trained workers were rated as feeling less depressed, suicidal and overwhelmed by the end of a call when compared to those receiving support from non-ASIST trained workers.

Efforts to increase the feasibility of conducting RCTs in crisis helplines will greatly strengthen the evidence-base for suicide prevention interventions. Below, we outline some of the main challenges to conducting RCTs in crisis helplines, and demonstrate how these may be overcome using an upcoming research project. In this proposed study, our team from Lifeline Australia and The University of Melbourne will conduct an RCT with the aim of evaluating a model of service delivery tailored to meet the needs of male callers.

1. Outcome measurement

There is scope to expand evaluation of novel interventions by prioritising self-report proximal outcomes measurement using validated scales over observational data collection, as mentioned above. Collecting self-report data has been challenged in all crisis helpline research, and is particularly important for researchers to tackle in the conduct of RCTs to evaluate key outcomes from callers' perspectives.

Improvements in technical telephony systems used by crisis centres can aid researchers by facilitating presentation of information to callers via interactive voice response (IVR) systems. Such advancements in technology provide an opportunity to integrate short self-report outcome measures into IVR systems using Likert scales selected by callers on numerical telephone keys (Matthieu et al., 2021). This methodology offers multiple advantages including reducing burden on helpline workers, mitigating concerns around data collection interrupting standard care practices (Tyson et al., 2016), and decreasing risk of bias in caller responses.

Additionally, there is space to further unpack the needs of callers to crisis helplines to realistically determine appropriate outcome measures based on those needs. In the case of our future RCT , formative qualitative work will be conducted with male callers to better understand what they hope to gain from crisis services. This will inform both the intervention

being tested, and the outcome measures selected in the trial. Although there is some qualitative inquiry in this space (Middleton et al., 2016; Williams et al., 2020), significant scope remains for in-depth understanding of the needs of callers to crisis helplines, and how they currently experience services. Garnering this first-person perspective from lived experience populations on caller needs and experiences will be instrumental in the development and subsequent evaluation of new and enhanced models of service delivery.

2. Randomisation

The crisis helpline context poses challenges with randomisation of participants into appropriate intervention arms. Randomising participants to an intervention or control group is unethical if standard care of support is compromised (or withheld) for any help-seeker. Consequently, our future RCT will use an active-comparator design and the intervention will be compared against Lifeline's standard care procedures. Further, the novel intervention is a service enhancement, as opposed to an entirely new (and untested) model of care. Via this approach, all trial participants – regardless of group allocation – will have access to standard care and emergency intervention procedures if required. Such an approach serves the purpose of minimising any potential risks of harm to participants due to the research while still allowing causal conclusions to be drawn.

Whilst an active-comparator design serves the imperative of providing high levels of support to all participants, it creates challenges for statistical power regarding detection of treatment effects due to similarities between the two comparators (Gould et al., 2013). Larger sample sizes are known to increase statistical power and allow for the detection of small but genuine effects (Sullivan & Feinn, 2012). Suicide prevention studies are often underpowered due to the difficulty and cost of implementing RCT approaches (Robinson et al., 2018). In this respect, crisis helpline research can afford unique advantages: working with Lifeline will

provide access to the sample size required to garner robust and sensitive findings due to a large number of callers available for trial participation, and the minimally intrusive nature of the trial proposed (i.e. short-term outcome measurement and no follow-up). Consequently, issues of differentiation between standard care and a given intervention may be less prominent than in trials conducted in other community healthcare settings with smaller sample sizes.

3. Informed consent

The requirement for informed consent is significantly challenged in the crisis helpline context by the anonymous nature of services, the help-seekers' urgent need for care, and potential diminished capacity to consent. A recent survey of Australian help-seekers calling Lifeline identified that nearly 60% reported suicidality as a reason for contact (O'Riordan et al., 2021). The likelihood that a high proportion of help-seekers are experiencing suicidal crisis at the time of the call is compounded by recent developments in neuroscience which indicate that suicidality is associated with brain changes that can impair an individual's problem-solving abilities and risk processing (Jollant et al., 2011; Keilp et al., 2013). There is a real possibility – and one that must be accommodated in study design – of diminished capacity to consent in the case of some callers who are in a suicidal crisis.

Based on the probability of help-seeker crisis at the time of a call, crisis helplines can meaningfully be considered as digital emergency services. Consequently, consent waivers can be applied: Australia's National Statement on Ethical Conduct in Human Research states that a waiver of consent may be granted on conditions including that involvement in the research carries no more than low risk, the benefits of participation justify any risks of harm, it is impracticable to obtain consent, and there is sufficient protection of privacy and confidentiality (National Health and Medical Research Council, 2018).

In keeping with the ethical considerations, there is precedent for allowing waivers on consent in emergency settings. For example, a recent systematic review indicated that 8.8% of high-impact RCTs published between 2014 and 2018 did not secure prospective informed consent, 66% of which involved emergent treatment in which the participant or family were unable to provide consent, and time was of the essence (Dhamanaskar & Merz, 2020). Research in emergency medical settings indicates that the majority of participants enrolled in studies without prospective consent found this acceptable following intervention (Dickert et al., 2013), conditional on the fact that studies are approved by an independent ethics review board (Kämäräinen et al., 2012).

There is a further and equally important argument that not only are waivers in this context *ethical*, but that *they are an important measure for mitigating risk*. In the time-pressured context of a crisis call, the increased burden of seeking consent carries the potential to put a distressed caller at more risk than not gaining prospective consent, and as such may be unethical. Following intervention and with the assurance that a caller is safe, consent can be sought to obtain outcome data at the end of a call. This approach allows for at-risk populations who are most likely to benefit from interventions to partake in research, while still ensuring access to emergency procedures to maintain participant safety. Further, given that crisis helplines are anonymous, there is no risk of confidentiality breaches which may pose ethical concerns.

We argue that crisis helplines are an appropriate setting to allow waivers on prospective consent with the understanding that the benefit of conducting RCTs in this setting outweighs any potential risks of harm to participants. Future research is required with callers to investigate the acceptability of waivers on prospective consent in this population. Taken together, the above example aims to demonstrate how researchers can work with crisis services to design realistic and tailored RCT methodologies to safely evaluate novel

interventions or service enhancements. Despite this, some challenges remain, and are discussed below.

An alternative solution – trial replication

In addition to the above considerations, further RCT features in the crisis helpline context require discussion. First, there are feasibility issues in defining specific trial inclusion and exclusion criteria to determine appropriate participant recruitment. The anonymity of helplines means that presenting issues of callers are often unknown, creating difficulties in recruiting appropriate participants relevant to the trial inclusion criteria. This limits the ability to test interventions with subpopulations in helpline contexts. Second, participant follow-up and measurement of medium to long-term outcomes remains a challenge due to time constraints and anonymity of crisis helplines.

Trial replication methodologies, used to test for causal relationships without conducting RCTs in a given population of interest, could aid in addressing these unresolved concerns. This technique has been demonstrated in insurance claims and electronic health records data (Franklin et al., 2021; Wing et al., 2021) and has the potential to be applied to suicide research. Although RCTs provide the highest standard of evidence, they are conducted with a subset of the population and are often criticised for being unrepresentative of the true population of interest, and underpowered to observe interactions among subgroups (Kennedy-Martin et al., 2015). Consequently, real-world studies can be used to complement the findings of trials and add confidence to the generalisability of results.

Trial replication methods involve developing a trial-analogous cohort in the population of interest and validate the findings against an RCT. This involves applying the trial criteria retrospectively to an observational cohort, and applying methods such as propensity score matching to address confounding (Rosenbaum & Rubin, 1983). Intervention

effects are then compared to those obtained from the trial and if they meet a pre-specified criterion, it can be assumed that such results are valid in the observational setting which contains the population of interest. Applied in the crisis helpline context, this would involve conducting an RCT in a separate population (e.g., those receiving ongoing face-to-face support where long-term follow-up is possible and outcome assessments are easier to implement), and then using the above methods to compare these data to observational data collected via a crisis helpline.

Trial replication methodologies provide an innovative way to establish causal effects of an intervention when an RCT is not feasible in the population of interest. This approach presents a major opportunity for the field to explore intervention strategies in high-risk populations and add confidence to results in a novel way. Further work is required to explore whether trial replication methods are feasible in crisis helplines, where the population is higher-risk and outcomes of interest are often subjective. If they do prove to be feasible, such methods may aid researchers in overcoming many of the practical barriers discussed.

Conclusion

In this editorial we argue that researchers in crisis helpline settings should consider evolving theoretical understandings of suicidality when selecting outcome measures, and that increased consistency across studies in outcome measurement is needed. Using an upcoming crisis helpline study as an example, we offer solutions to common challenges in RCT conduct, and suggest considerations around novel ways of conducting suicide intervention research with high-risk populations. High-quality, reliable research in crisis helplines is a necessity in order to understand and improve the impact of suicide prevention interventions in this setting.

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