BMJ Open

Investigating the feasibility of a social support intervention in self harm and suicidal behaviour: A protocol for a randomised controlled trial delivering a Social Work Intervention following Self Harm (SWISH)

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2016-012043
Article Type:	Protocol
Date Submitted by the Author:	24-Mar-2016
Complete List of Authors:	Ahmed, Nilufar; Swansea University College of Human and Health Sciences, Public Health, Policy and Social Sciences Jones, Richard; Hywel Dda Health Board John, Ann; Swansea University, Farr Institute Islam, Saiful; Swansea University, College of Medicine Anderson, Pippa; Swansea University, Centre for Health Economics Huxley, Peter; Bangor University
Primary Subject Heading:	Mental health
Secondary Subject Heading:	Health services research, Mental health
Keywords:	randomised controlled trial, self harm, intervention, depression, social support, suicide prevention

Investigating the feasibility of a social support intervention in self harm and suicidal behaviour: A protocol for a randomised controlled trial delivering a Social Work Intervention following Self Harm (SWISH)

Nilufar Ahmed*[1], Richard Jones[2], Ann John[1], Saiful Islam[1], Pippa Anderson[1], Peter Huxley[3]

Abstract

Introduction: Self harm a strong predictor for suicide. Risks for repeat behaviour are heightened in the aftermath of an index episode. There is no consensus on the most effective type of intervention to reduce repetition. Treatment options for patients who do not require secondary mental health services include: no support, discharge to General Practitioner, or referral to primary care mental health support services. The aim of this study is to assess whether it is feasible to deliver a social intervention after an episode and whether this can reduce depressive symptoms and increase sense of wellbeing for patients who self harm.

Methods: This is a non-blinded parallel group randomised clinical trial. One hundred and twenty patients presenting with self harm and/or suicidal ideation to mental health services over a twelve month period who are not referred to secondary services will be randomised to either intervention plus treatment as usual (TAU), or control (TAU only). Patients are assessed at baseline, 4 weeks and 12 weeks with standardised measures to collect data on depression, wellbeing and service use. Primary outcome is depression scores; secondary outcomes are wellbeing scores and use of services. The findings will indicate whether a rapid response social intervention is feasible and can reduce depression and increase wellbeing among patients who self harm and do not require secondary services.

Ethics and dissemination: Ethical approval was granted by the UK National Health Service (NHS) Ethics Committee process (REC 6: 14/WA/0074). The findings of the trial will be disseminated through presentations to the participating Health Board and partners, peer-reviewed journals, national and international conferences.

Trial registration: The trial is registered with the International Standard Randomised Controlled Trial Network (ISRCTN 76914248); and the UK Clinical Research Network (16229)

Keywords: Randomised controlled trial, Self Harm, Suicide, Intervention, Social wellbeing, Social support, Social networks, Depression

*Corresponding Author:
Dr Nilufar Ahmed
27 Haldane Building
College of Human and Health Sciences
Swansea University, Singleton Park, Swansea, SA2 8PP
01792 602819
n.ahmed@swansea.ac.uk

[1]Swansea University
[2]Hywel Dda University Health Board
[3]Bangor University

Strengths and limitations of the study

- Development of an intervention for people who have little or no support following self harm.
- A cost-effective intervention that can work alongside existing services, supporting patients during a vulnerable time and keeping them engaged whilst they are awaiting assessment from other services.
- Social linkage relies on access to services and transport
- Unblinded trial

Background

Self-harm is the strongest risk factor for future suicide[1] resulting in over 200,000 hospital presentations annually in England and Wales[2, 3]. Self harm is associated with high personal, social and medical costs[4]. Repetition is common, with between 15-25% re-presenting to the same hospital within a year of the index episode[5]. The highest risk of repeat self harm is within3-6 months after the index episode[6] with the risk for suicide in the year following self harm almost 50 times higher than in the general population[7].

The escalated risks associated with self harm have led to numerous interventions to reduce further self harm and suicidal behaviour. These vary significantly across content and across target groups; with no single type of intervention found to deliver consistent results. The link between a mental health condition and self harm is strong[8] with depressive symptoms prevalent amongst those with self harm and suicidal ideation[9]. Given this, the majority of interventions targeted at individuals who self harm are based on psychological and medical approaches[10]. Addressing these immediate needs are prioritised over the exploration of social stressors that may have been implicated in the presenting episode. Whilst this responds to the presentation it does not adequately explore the social milieu of the patient which may have been precipitous in the self harm behaviour and therefore may be a recurring antecedent for self harm.

Despite NICE guidelines explicitly stating that patients who present with self harm should receive a psychosocial assessment[11], this is not routinely offered[12]. Presentations to hospital tend to prioritise risk factors to determine admission, referral or discharge above psychosocial needs. A lack of such exploration leaves much of the psychological impact of social situations under examined. Studies report that as many as 70% of self harm episodes are triggered by interpersonal problems[13]. A mental health condition in itself does not mean self harm will always be present; many people with a mental health diagnosis do not self harm or have suicidal thoughts[14,15]; and not all of those who present with self harm have, or are diagnosed with, a psychological condition. Self harm may be a response to distress resulting from social factors[16]. For such patients, the lack of medical or psychological care needs often results in receiving little or no support from health care services, with signposting to community services or discharge to General Practitioner (GP) being the main course of management. Supporting individuals to deal with stressors and enabling them to better manage stressors may help alleviate their impact and thus reduce rates of self harm as a response to ongoing or repeated stress.

The importance of recognising and responding to social factors in self harm and suicide prevention has been described in the literature[17]. There is global evidence of significant increases in suicide rates following economic recession[18] with unemployment being strongly linked with suicide for men and women[17]. Research has also linked an elevated risk of suicide with isolation and a lack of social integration[19].

There is little effective primary care prevention for patients who self harm either as a first episode or repeatedly[20]. Findings from contact interventions vary, with some reporting long term positive impacts[21,22,23,24]. Such interventions offer a cost-effective way of supporting individuals by reducing a sense of isolation and increasing a sense of social connectedness; it has been argued that perceived connectedness can reduce suicidal ideation[24]. An elevated sense of support may encourage help seeking at times of crisis[24].

There is a need for further evidence for the effectiveness of social interventions. This study draws on findings from studies which find increasing social support can support those who self harm and reduce suicide rates[21]. An Australian study[25] reported a social intervention focussing on connecting individuals to relevant and available support led to a reduction in depression scores and an increase in wellbeing. This study is designed in a similar way to offer a brief non-psychological and non-medical intervention delivered by trained practitioners.

The aim of this study is to assess whether a social intervention is beneficial for patients who present with self harm and/or suicidal ideation but are not referred to secondary services. The intervention focuses on social factors, and goes beyond signposting with assertively linking the individual to relevant support agencies that already exist. By doing so, the individual becomes embedded in to a support network which they can draw on at future times of stress. The primary outcome measure is the Beck Depression Inventory (BDI-II)[26]. Secondary outcomes assess whether a social intervention leads to overall increase in wellbeing, as measured by the Manchester Short Assessment of Quality of Life (MANSA)[27]; and whether the intervention reduces rates of representation to mental health services as measured by the Client Service Receipt Inventory (CSRI)[28] an adaptable tool commonly used to measure service use and further follow up data collection on service use.

METHOD

Design and setting

This is a randomised controlled trial (RCT) conducted by Swansea University in partnership with Hywel Dda University Health Board (HDUHB) running between January 2015 – March 2016 in Carmarthenshire, West Wales. The trial delivers a brief contact intervention to patients over 18 who present to Mental Health Services who are assessed to be low risk, and would ordinarily be referred back to primary care and/or community services. Patients are randomised to the intervention or control group. The intervention is a 4-6 week programme of face-to-face and phone call contact tailored to meet the needs of the individual in addition to Treatment As Usual (TAU). The control arm is just Treatment As Usual, whereby patients are either discharged with no further support or referred to primary care for ongoing care. The full duration of patient participation is 12 weeks with assessments collecting standardised measures for depression, wellbeing, and service use conducted for all patients at baseline, 4 weeks and 12 weeks. Where possible a 6 month follow up using the same measures will be sought.

Study population

Patients who present to Mental Health Services (either directly to hospital, or indirectly through referral from General Practitioner to Local Primary Mental Health Support Services) with self harm and/or suicidal ideation are assessed by Mental Health Practitioners at these sites and those thought suitable for SWISH are referred to SWISH in addition to their treatment as usual. A SWISH worker conducts a further eligibility test based on inclusion and exclusion criteria before inviting a patient

who meets the requirements to participate. Patients are given a study information leaflet and time to consider whether they would like to take part. Written consent is obtained by the research assistant prior to baseline data collection. Once baseline data has been collected patients are randomly assigned to either intervention or control.

Inclusion criteria:
Person 18 or over who presents to Mental Health Services with self-harm and/or suicidal ideation

Exclusion criteria:
Anyone who, following assessment by a Mental Health Practitioner, is:
- unable to give informed consent
- requires admission to a mental health inpatient unit
- requires secondary mental health services
- assessed as high risk for violence
- known or assessed to have a severe mental illness and require other services
- is under a current and active care and treatment plan with Adult Mental Health Services
- is unable to communicate in English

At any point if a recruited patient meets any of the exclusion criteria they are withdrawn from the study, but their anonymised will be retained for analysis.

Power and sample size
The power analysis is based on the primary outcome measure, BDI-II score. Based on published reviews and papers, a five to ten percent change in the BDI-II score represents a clinically important difference and the standard deviation varies between 6 to 10 [29,30,21] which provides an effect size of approximately 0.53. To detect a five to ten point difference in the BDI mean score between intervention and the control conditions, with 80% power requires a sample size of 120 (60 in each arm of the trial).

Randomisation
We performed an individual randomisation of the patients from study population who met the inclusion-exclusion criteria. Patients are randomised after completion of baseline assessment by the Intervention Practitioner using an online randomisation tool managed by Swansea Trials Unit. The selected patient are randomised with a ratio of 1:1 to intervention and control and used the random number generated from *New Cambridge Statistical Table*[32].

Intervention
The intervention is a 4-6 week contact programme which is a mix of face-to-face and telephone contact. It deliberately steers away from being a psychological or medical service; rather it is based on linking individuals into social support networks and encouraging access to, and engagement with, relevant services. It is not a replacement service for support services already in place. It encourages patients to engage with existing services. As such, as long as patients are not receiving support from secondary mental health services (an exclusion criteria based on higher support needs of secondary mental health service users); there is no contraindication to involvement with SWISH.

An awareness of local third sector services is key to the role of practitioner. The intervention can be delivered by a skilled individual who has experience of working with people with mental health issues. The practitioners delivering the intervention in this trial have worked in mental health

services but are not registered mental health practitioners. They have experience of working in Carmarthenshire within mental health services and/or developing mental health services for vulnerable populations. By not requiring practitioners to hold registrations, the intervention is more cost effective to deliver as it relies on locality-based training and awareness. The practitioners receive clinical supervision from an Advanced Nurse Practitioner in mental health services. Formal supervision is once a fortnight or more depending on requirements; the supervisor is available at all times on the phone for immediate questions. The intervention encourages individuals to link with local services. In this trial some of the agencies patients are linked into include Men's Shed projects, adult education courses, knitting groups and volunteering services; as well as services supporting individuals with drug and alcohol issues and domestic abuse. The choice of service is decided alongside the patient based on the type of support and engagement they would like. The intervention primarily focuses on the social dimensions of a person's life; the medical and psychological needs of the patient will have been assessed prior to the patient's referral to SWISH. If at any time during the intervention the practitioner is concerned that these needs may be escalating and require specialised support, this will be discussed with the clinical supervisor and they will be referred accordingly; and SWISH will continue to support the patient for the duration of the intervention, or until they meet the exclusion criteria and are engaged with relevant support services.

The first patient-practitioner contact is as soon as possible after baseline has been collected by a research assistant. At the first meeting the patient is encouraged to discuss recent events and explore the reasons which they feel led to their current situation. This meeting typically lasts about an hour. The practitioner works with the patient to identify the main social issues they feel precipitated this and discuss relevant agencies that may be able to offer support and information. A plan of action is then worked out with the patient where the patient is given suggestions for services that they can link in with. Treatment as usual for patients with low or no mental health history and risk who present to the hospital Emergency Department is usually referral back to GP; although some might be signposted to services in the community usually by way of leaflets provided. This intervention goes beyond signposting to assertively link the patient with relevant services to embed them within a supportive network at a time of emergency and vulnerability to try and ameliorate the negative impact of the self harm episode. This 'assertive community linkage' is the basis for the intervention. It encourages patients to contact relevant community agencies who can provide specialised support and establish a supportive resource to help manage future periods of stress.

Subsequent follow up contacts are a mix of face-to-face and telephone contacts depending on agreement and discussion with patient. Patients are seen at a location that is convenient to them, this includes home visits, however as part of the community linkage patients are encouraged to engage outside of the home and so meetings are held in local spaces including GP surgeries, coffee shops and arts centres. Details of all contacts are logged on the FACE electronic recording system used by Hywel Dda University Health Board as their health care notes recoding system. The number and nature (face to face or telephone) and length of contacts vary depending on patient need and are mutually decided between patient and practitioner. The minimum number is four and the maximum is usually six, with the first and final contact always being face to face. As this is a feasibility study we have been flexible with the final number of sessions to accommodate patients who may be waiting for another service. In this situation SWISH provides support until they are engaged with another provider. This has resulted in up to eight sessions in three cases.

This is an important feature of the intervention where as well as providing a stand-alone service linking individuals to community services; it acts as a bridging service for patients. Patients referred

to Local Primary Mental Health Support Services and those who have been referred to other (non-secondary) mental health support services such as psychological therapy services typically face a 4-8 week wait for assessment. The intervention provides a point of regular contact and support during this waiting this period.

Control

The control group receive treatment as usual from the service they presented to. This ranges from no action, discharge to GP, signposting to community services and/or referral to psychological therapy services. These treatments do not conflict with SWISH.

Assessments

All patients complete assessments at Baseline (before randomisation), 4 weeks and 12 weeks. Those who fall in to the six month period whilst the study is running are invited to complete a 6 month assessment.

Baseline assessments

The baseline assessment consists of the BDI-II, MANSA and CSRI. Patients are asked to complete these questionnaires as soon as possible after they consent. The questionnaires are designed to be self-completed, however the researchers read out the questions and fill in the responses where requested by patients. Researchers note whether they were required to read out any/all questions, and any questions patients have asked for clarity or elaborated upon while completing the questionnaire pack. Patients are given a £10 voucher for the time after completing the baseline assessment.

Follow up assessments

Follow up assessments are conducted with the same questionnaires (BDI-II, MANSA, CSRI) at 4 weeks and 12 weeks. Patients are given no incentive at the 4 week assessment, but those who complete the third assessment at 12 weeks are given a £20 voucher for their time. Early recruits are invited to take part in a 6 month assessment where possible, and a further £10 voucher is given for their time.

All contact with patients is recorded on the health board electronic patient contact recording system.

Patient evaluation and qualitative follow up

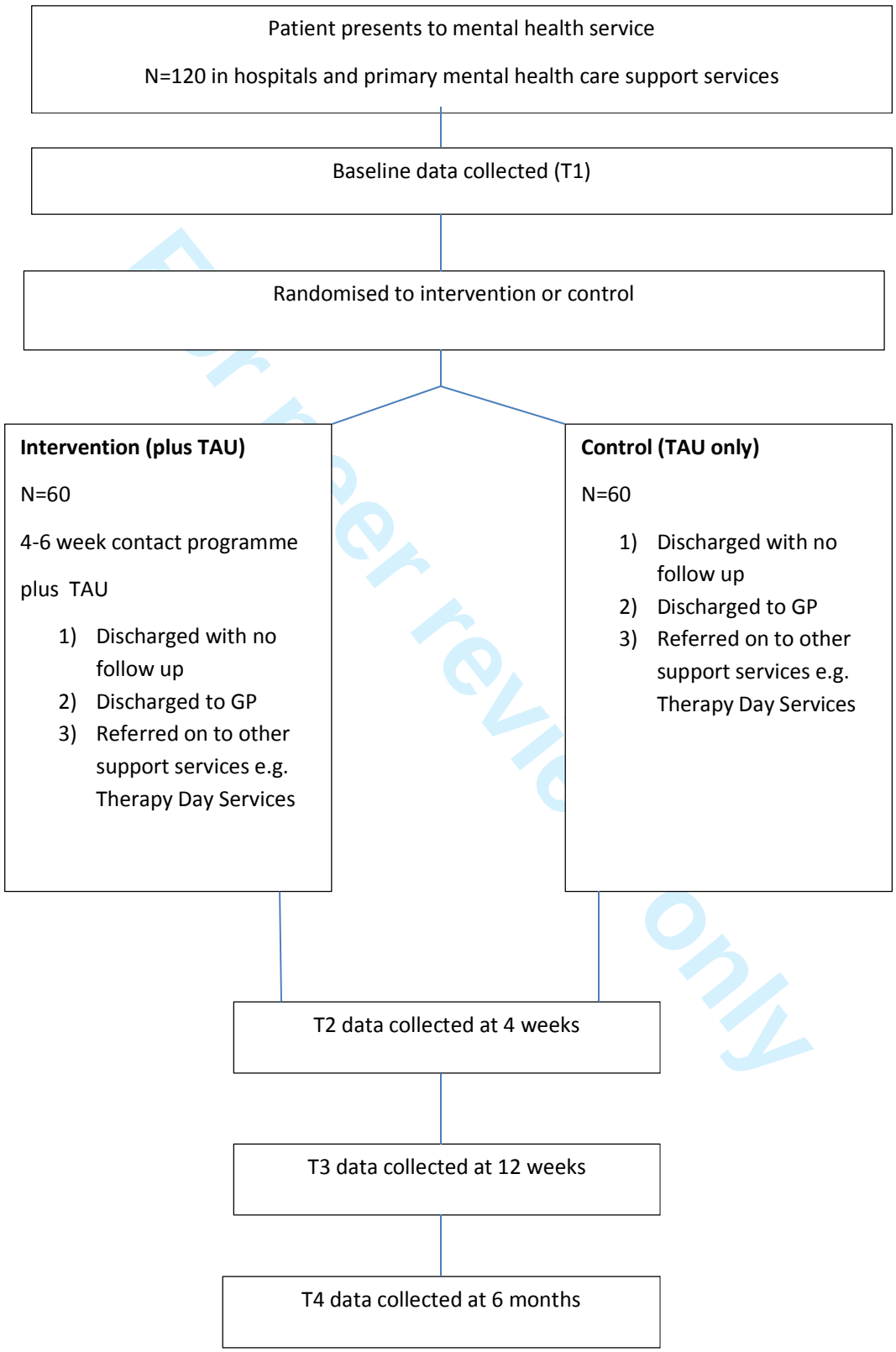
At the 12 week data collection patients are asked to complete an evaluation form of their experience of SWISH. There is room for additional comments. The researcher asks for the feedback on the contact and this is recorded verbatim. Initially this data was only included for intervention patients, however we have begun to collect it for control as well after control patients commented on the support they felt they were receiving from the researcher collecting assessment data.

Blinding

There is no blinding of researchers or participants. The information sheet clearly states the intervention is a 4-6 week contact programme. The researcher advises all patients that the intervention practitioner will be in touch within a few days if they are randomised to the intervention. It proved impractical and almost impossible to blind the researcher conducting the

assessments as at week four there was often a clash with intervention meetings for the patient. It would be preferable for all assessments to be collected by the researcher, however due to staffing issues in this trial and to minimise the time commitment on the part of the patient and maximise data collection, intervention patients are given the option to complete the 4 week assessment at an intervention meeting with the practitioner rather than the researcher.

Study chart



Trial Management Group

A Trial Management Group whose members include study applicants (academics and health board practitioners), service users, and representatives of community organisations meets once a quarter to monitor progress and discuss any issues arising.

Analysis

Statistical analysis

Our analysis will be based on the primary and secondary outcome measures which are the BDI-II (Beck Depression Inventory – II) score and MANSA (Manchester Short Assessment of Quality Of Life) and CSRI (Client Services Receipt Inventory). The hypothesis of interest is that the change scores on these outcome measures will be significantly different in the intervention group compared to the control group. We shall analyse changes in all outcome measures between baseline and follow-up at 4 weeks, 12 weeks and (where collected) 6 months by adopting repeated measures analysis of variance. We shall use the pertaining values of the outcome measure under analysis and consider participants' demographic characteristics (e.g. age, marital status, sex education level) as covariates. Since both the BDI-II score and MANSA are well validated and used outcome measures respectively for depression and 'Quality of Life', we would not require checking their internal consistency.

We will adopt the intention-to-treat (ITT) population, consisting of all subjects randomly assigned to the intervention and control. To deal with the missing values, we shall summarise the frequency of missing data for each variable, which affects effective sample size and hence statistical power. If there is no reason to suspect that data are not Missing Completely At Random (MCAR), we shall consider the use appropriate imputation methods to ameliorate the problem of missing data; otherwise, the Trial Statistician and Chief Investigator will further discuss patterns in missing data. Outcome descriptions, summaries and comparisons will be expressed in accordance with appropriate CONSORT guidelines[33], including estimates with 95% confidence intervals to summarise two-tailed tests at the 5% significance level

Health Economics

Health service resource use in primary care, secondary care and the community is collected using the CSRI from participants in both arms of the trial at baseline, 4 weeks, 12 weeks and 6 months. Questions will relate to all health service contacts (hospital appointments, hospital stays, GP contacts, visiting nurse appointments, etc.) and prescription medicines dispensed during the trial period. Patient recall has been shown to be a valid method for collecting health service resource use data over this period (and, as clinical records are often fragmented, and sometimes unavailable, across different parts of the health service) patient-reported data is likely to remain more readily available and less costly to collect for research purposes[34] . A descriptive analysis of CSRI data, along with estimates of the cost of providing the intervention, will provide a comparison of participant resource use between intervention and control groups, and will provide indicators of the main resource use (and associated costs) drivers of those receiving the intervention.

The CSRI data will be summarised and presented descriptively. The resources utilised and associated costs will be summarised. The costs of the intervention will be estimated. These data will be used to compare the costs of the intervention and usual care and to inform the calculation of incremental costs. The sources of costs will be fully referenced to aid transparency of the analysis. Where possible, published unit costs will be used (e.g. PSSRU Costs of Health and Social Care, British

National Formulary, NHS reference costs) using the most recent published sources - 2014/15. Costs (mean and SD and/or 95% confidence intervals or non-parametric equivalent (median and IQRs) will be presented.

Dissemination

Findings will be fed back to the Health Board and to the third sector through presentations and contributions in local publications. Outcomes will be published in peer- reviewed journals and at national and international conferences

DISCUSSION

This paper describes the study protocol for a feasibility study for a randomised controlled trial of a social intervention for people who present with self harm or suicidal ideation and do not require secondary mental health services.

Several limitations apply to this study. Firstly, interventions tend to have a high attrition rate. Dropout can introduce a selection bias and pose a threat to validity. However, we are able to report a high rate of successful intervention completion at 77% across the whole sample. If those who were withdrawn from the study (due to meeting exclusion criteria) are excluded, the completion rate for all those eligible to complete the intervention rises to 83%.

Secondly, the services that SWISH is able to provide are limited. Encouraging social linkage is largely dependent on the availability of relevant options for individuals. In a large, predominantly rural county[35], there are limited choices, which are further reduced if there is no access to transport. A social linkage programme will be able to offer more resources in areas where there are more agencies and community services to engage with. The location and accessibility of services may affect the generalisability of findings to urban populations.

Thirdly, whilst the assessments are intended to be self completed, low literacy levels meant that a substantial number were read out by the researcher. This may have affected responses.

Fourthly, as discussed above, the study was conducted unblinded. Attempts were made to blind the researcher collecting assessments, however this was not practical.

However, even with limitations, the findings will offer an insight in to the applicability of a social intervention to sit alongside medical and psychological interventions. SWISH offers a short term crisis response to engage patients whilst they are waiting for referrals to medical and community services. Often there are 4-8 week waiting lists to be seen by other services. SWISH fills this void and provides support to individuals at a vulnerable time; by engaging with patients whilst they are waiting for other appointments it can help reduce rates not attending appointments with other health and social care services.

TRIAL STATUS

In follow up period of data collection.

FUNDING AND REGISTRATION

The trial is funded by Health and Care Research Wales and sponsored by Swansea University. The trial is registered with the International Standard Randomised Controlled Trial Network (ISRCTN 76914248); and the UK Clinical Research Network (16229)

AUTHOR CONTRIBUTIONS

PH conceived the study in conjunction with RJ and AJ; RJ is clinical supervisor and provides expertise and supervision to practitioners. NA is Chief Investigator and drafted the protocol, designed the study and organised and supervised implementation. AJ and PH provide methodological expertise. SI is trial statistician and developed the statistical analysis strategy and PA developed the health economics strategy. All authors contributed to the preparation of this manuscript, providing comments on drafts approving the final version.

COMPETING INTERESTS

None.

References

1. Cavanagh, J.T.O., Carson, A.J., Sharpe, M., & Lawrie, S.M. (2003) Psychological autopsy studies of suicide: a systematic review, *Psychol. Med*., 33, 395–405

2. Clements, C., Turnbull, P., Hawton, K., Geulayov, G., Waters, K., Ness, J., ... & Kapur, N. (2016). Rates of self-harm presenting to general hospitals: a comparison of data from the Multicentre Study of Self-Harm in England and Hospital Episode Statistics. *BMJ open*, *6*(2), e009749.

3. Welsh Govt (2015) New suicide prevention plan to support most vulnerable, http://www.wales.nhs.uk/news/38065

4. Sinclair, J. M., Gray, A., Rivero-Arias, O., Saunders, K. E., & Hawton, K. (2011). Healthcare and social services resource use and costs of self-harm patients. *Social psychiatry and psychiatric epidemiology*, *46*(4), 263-271

5. Owens, D., Horrocks, J. & House, A. (2002) Fatal and non-fatal repetition of self-harm. Systematic review. *British Journal of Psychiatry*, 181, 193 -199

6. Gilbody, S., House, A., Owens, D,. The early repetition of deliberate self harm. *Journal of the Royal College of Physicians of London* 1997; 31:171–172

7. Hawton, K., Bergen, H., Cooper, J., Turnbull, P., Waters, K., Ness, J., & Kapur, N. (2015). Suicide following self-harm: Findings from the Multicentre Study of self-harm in England, 2000–2012. *Journal of affective disorders*, *175*, 1+ 47-151.

8 . Chartrand, H., Bhaskaran, J., Sareen, J., Katz, L. Y., & Bolton, J. M. (2015). Correlates of Nonsuicidal Self-Injury and Suicide Attempts Among Tertiary Care, Emergency Department Patients. *Canadian journal of psychiatry. Revue canadienne de psychiatrie*, *60*(6), 276-283.

9. Skegg, K. (2005). Self-harm. *The Lancet*, *366*(9495), 1471-1483.

10. National Collaborating Centre for Mental Health (UK). Self-Harm: Longer-Term Management. Leicester (UK): British Psychological Society; 2012. (NICE Clinical Guidelines, No. 133.) 7, PSYCHOLOGICAL AND PSYCHOSOCIAL INTERVENTIONS. Available from: http://www.ncbi.nlm.nih.gov/books/NBK126779/

11. National Institute for Clinical Excellence. Self-Harm: The Short Term Physical and Psychological Management and Secondary Prevention of Self-Harm in Primary and Secondary Care. 2004. p. *National Institute for Clinical Excellence*, London (2004).

12. Cooper, J., Steeg, S., Bennewith, O., Lowe, M., Gunnell, D., House, A., ... & Kapur, N. (2013). Are hospital services for self-harm getting better? An observational study examining management, service provision and temporal trends in England. *BMJ open*, *3*(11), e003444.

13. Bancroft, J., Skrimshire, A., Casson, J., Harvard-Watts, O., & Reynolds, F. (1977). People who deliberately poison or injure themselves: their problems and their contacts with helping agencies. *Psychological medicine*, *7*(02), 289-303.

14. Ougrin, D., & Latif, S. (2011). Specific psychological treatment versus treatment as usual in adolescents with self-harm. *Crisis*, 32, pp. 74-80

15. Hepp, U., Wittmann, L., Schnyder, U., & Michel, K. (2004). Psychological and psychosocial interventions after attempted suicide. *Crisis*, *25*(3), 108-117

16. Hawton, K., Saunders, K. E., & O'Connor, R. C. (2012). Self-harm and suicide in adolescents. *The Lancet*, *379*(9834), 2373-2382.

17. Kposowa, A. J. (2000). Marital status and suicide in the National Longitudinal Mortality Study. *Journal of epidemiology and community health*, *54*(4), 254-261.

18. Barr, B., Taylor-Robinson, D., Scott-Samuel, A., McKee, M., & Stuckler, D. (2012). Suicides associated with the 2008-10 economic recession in England: time trend analysis.

19. Stack, S. (2000). Suicide: a 15-year review of the sociological literature part II: modernization and social integration perspectives. *Suicide and Life-Threatening Behavior*, *30*(2), 163-176.

20. Webb, L. (2002). Deliberate self-harm in adolescence: a systematic review of psychological and psychosocial factors. Journal of Advanced Nursing, 38, 235–244

21. De Leo, D., Buono, M. D., & Dwyer, J. (2002). Suicide among the elderly: the long-term impact of a telephone support and assessment intervention in northern Italy. *The British journal of psychiatry*, *181*(3), 226-229.

22. Milner, A. J., Carter, G., Pirkis, J., Robinson, J., & Spittal, M. J. (2015). Letters, green cards, telephone calls and postcards: systematic and meta-analytic review of brief contact interventions for reducing self-harm, suicide attempts and suicide. *The British Journal of Psychiatry*, *206*(3), 184-190.

23. Kapur, N., Cooper, J., Bennewith, O., Gunnell, D., & Hawton, K. (2010). Postcards, green cards and telephone calls: therapeutic contact with individuals following self-harm. *The British Journal of Psychiatry*, *197*(1), 5-7

24. Chioqueta, A. P., & Stiles, T. C. (2007). The relationship between psychological buffers, hopelessness, and suicidal ideation: identification of protective factors. *Crisis*, *28*(2), 67-73.

25. Petrakis, M., & Joubert, L. (2013). A social work contribution to suicide prevention through assertive brief psychotherapy and community linkage: Use of the Manchester Short Assessment of Quality of Life (MANSA).*Social work in health care*, *52*(2-3), 239-257

26. Beck, A. T., Steer, R. A., & Brown, G. K. (1996). Beck depression inventory-II. *San Antonio, TX: Psychological Corporation*, b9.

27. Priebe, S., Huxley, P., Knight, S., & Evans, S. (1999). Application and results of the Manchester Short Assessment of Quality of Life (MANSA).*International journal of social psychiatry*, *45*(1), 7-12

28. Beecham, J., & Knapp, M. (2001) Costing psychiatric interventions. In: Thornicroft G, ed. Measuring Mental Health Needs, 2nd edn. London: Gaskell, pp200–224

29. Baguley, T. (2012). *Serious stats: A guide to advanced statistics for the behavioral sciences*. Palgrave Macmillan.

30. Frasure-Smith, N., Lespérance, F., Prince, R. H., Verrier, P., Garber, R. A., Juneau, M., ... & Bourassa, M. G. (1997). Randomised trial of home-based psychosocial nursing intervention for patients recovering from myocardial infarction. *The Lancet*, *350*(9076), 473-479.

31. Merrill, R. M. (2016). *Statistical Methods in Epidemiologic Research*. Jones & Bartlett Publishers.

32. Lindley, D. V., & Scott, W. F. (1984). New Cambridge Statistical Tables Cambridge.

33. Schulz, K. F., Altman, D. G., & Moher, D. (2010). CONSORT 2010 statement: updated guidelines for reporting parallel group randomised trials. *BMC medicine*, *8*(1), 1.

34. Ridyard, C. & Hughes, D. (2013) Review and the use of resource instruments based on patient recall in relation to other methods pf resource use estimation. *Trials*, 14, 1-1

35. Periman, B. Hartman, E. A. & Bosak, J. (1984) A study of mental health administrators and systems utilising a four-part urban/rural taxonomy. *Community Mental Health Journal.* 20(3), 202-211

STUDY PROTOCOL

Study Title	Social Work Intervention following Self Harm
Study Acronym	SWISH
Sponsor/ Ref	Swansea University/ SKR518
Funder/Ref	NISCHR Social Care Award / SCR-12-05
Ethics Board / Ref	Wales REC 6 / 14/WA/0074
IRAS Ref	139510
ISRCTN	ISRCTN76914248
UK CRN	16229
Protocol version and date	V.4 November 2015
Protocol produced by	Dr Nilufar Ahmed
Grant awarded:	£257, 279
Start date:	1 October 2013
Original end date:	30 September 2015
Revised end date:	31 March 2016 – VTC awarded 28/04/14

Chief Investigator

Dr Nilufar Ahmed
College of Human and Health Sciences
27 Haldane Building
Swansea University
Singleton Park, Swansea, SA2 8PP
n.ahmed@swansea.ac.uk

Contents

APPLICANTS

Chief Investigator: Dr Nilufar Ahmed
College of Human and Health Sciences
112 Vivian Tower
Swansea University
Singleton Park
Swansea
SA2 8PP
n.ahmed@swansea.ac.uk

Co-applicants:

Co-applicant:
Current Job Title: Professor Peter Huxley
Institution/Organisation: Professor of Mental Health Research
Contact address: Bangor University
Email: School of Social Sciences, Gwynedd, LL57 2DG
Telephone number: P.J.Huxley@bangor.ac.uk
Role in project: 01978 727142
To provide consultancy advice on all elements of the project. Trial Management Group, report writing, conference presentations, dissemination activities.

Co Applicant: Dr Ann John
Current job title: Clinical Senior Lecturer in Public Mental Health
Institution / organisation: Swansea University
Contact address: College of Medicine, Singleton Park, SWANSEA SA2 8PP
Email: A.John@swansea.ac.uk
Telephone: 01792 602568
Role in project: Trial management group; policy advice, report writing and dissemination activities

Co-applicant: ~~Dr Sherrill Evans~~
~~Current job title:~~ ~~Senior Lecturer in Social Work and Social Care Research~~
~~Institution / organisation:~~ ~~Swansea University~~
~~Contact address:~~ ~~Mental Health Research Team, 3rd floor ILS2, Singleton Park, SWANSEA SA2 8PP~~
~~Email:~~ ~~S.Evans@swansea.ac.uk~~
~~Telephone:~~ ~~01792 602605~~
Role in project: None. Retired before start of project

Co-applicant: ~~Dr Philip Jones~~
~~Current job title:~~ ~~Lecturer in Mental Health Informatics~~
~~Institution / organisation:~~ ~~Swansea University~~
~~Contact address:~~ ~~College of Medicine, Singleton Park, SWANSEA SA2 8PP~~
~~Email:~~ ~~P.A.Jones@swansea.ac.uk~~

~~Telephone:~~	~~01792 602190~~
Role in project:	~~Trial management group; connection with NISCHR MHRNC suicide research and development group; analysis advice, report writing and dissemination activities~~ RETIRED SINCE START OF PROJECT
Co-applicant:	~~Professor Ceri Phillips~~
Current job title:	~~Head of Research, College of Human & Health Sciences; Professor of Health Economics, Swansea Centre for Health~~
Institution / organisation:	~~Swansea University~~
Contact address:	~~College of Human and Health Sciences, Singleton Park, SWANSEA SA2 8PP~~
Email:	~~C.J.Phillips@swansea.ac.uk~~
Telephone:	~~01792 518544~~
Role in project:	~~Advisor on CSRI analysis; health economics advice for full trial; report writing and dissemination activities~~ UNABLE TO COMMIT TO STUDY RESPONSIBILITIES
Co-applicant:	Professor Lynette Joubert
Current job title:	Professor
Institution / organisation:	Melbourne University
Contact address:	Rm 510, 234 Queensberry St, Melbourne, Parkville
Email:	ljoubert@unimelb.edu.au
Telephone:	8344 9417
Role in project:	To provide information and training on Australian study to allow adaptation. To collaborate in publications and provide data sets from Australian study to allow comparability of findings for publication.

COLLABORATORS:

Collaborator:	Mr Richard Jones
Current job title:	Advanced Nurse Practitioner
Institution / organisation:	Hywel Dda Health Board
Contact address:	Y Delyn/Morlais Ward, Glangwili Hospital, CARMARTHEN SA31 2AF
Email:	Richard.Jones@wales.nhs.uk
Telephone:	01554 745760
Role in project:	Clinical Supervisor and Clinical Manager for SWISH staff. Trial management group; links to the hospital services and assessment management of self-harm victims; links to service user organisations in Carmarthen; link to LHB; accessing hospital data, report writing and dissemination activities.

Abbreviations and Acronyms

A&E	Accident and Emergency Department
AK	Ashrafunessa Khanom (Research Assistant)
CA	Co Applicant
CD	Charlotte Davies (Research Assistant)
CI	Chief Investigator
CRHT	Crisis Resolution Home Team
DSH	Deliberate Self Harm
ED	Emergency Department
GCP	Good Clinical Practice
GGH	Glangwili General Hospital
GP	General Practitioner
HDUHB	Hywel Dda University Health Board
RJ	Richard Jones (HDUHB Lead and SWISH Clinical Supervisor)
LPMHSS	Local Primary Mental Health Support Services
MHS	Mental Health Services
NA	Nilufar Ahmed (Chief Investigator)
NHS	National Health Service
NISCHR	National Institute of Social and Health Care Research
PA	Psychosocial Assessment
PPH	Prince Phillips Hospital
R&D	NHS Trust Research and Development Department
RA	Research Assistant
REC	Research Ethics Committee
SAIL	Secure Anonymised Information Linkage
STU	Swansea Trials Unit
SDP	St David's Park
SPED	Suicide Prevention in the Emergency Department
SWISH	Social Work Intervention following Self Harm
TMF	Trial Master File
TMH	Together for Mental Health
TMG	Trial Management Group
WG	Welsh Government
WWAMH	West Wales Action for Mental Health
WWORTH	West Wales Organisation for Rigorous Trials in Health

TRIAL SUMMARY

This is a randomised controlled trial conducted by Swansea University in partnership with Hywel Dda University Health Board running between January –December 2015. The trial delivers a brief contact intervention to patients over 18 who present to Mental Health Services in Carmarthenshire, West Wales who are assessed to be low risk, and would ordinarily be referred back to primary care and/or community services. This is a feasibility based on an Australian study which has reported favourable outcomes for patients who present to the Emergency Department with self harm, including more positive outlook following the intervention and a reduction in BDI scores and re-presentation with self harm. It is not possible to wholly replicate the Australian study based on a different healthcare system in the UK, so we have broadened the referral base to include referrals to Mental Health Services as well as hospital presentations. It is anticipated that a brief intervention may help support patients at a vulnerable time and help increase wellbeing and buffer against repeat behaviour. The intervention is a 4-6 week programme of face-to-face and phone call contact in addition to treatment as usual. The control arm, is treatment as usual, whereby patients are referred back to primary care for ongoing care. The full duration of patient participation is 12 weeks with assessments collecting standardised measures for depression, wellbeing, and service use conducted for all patients at baseline, 4 weeks and 12 weeks. The Australian study also collected this data at 6 months. We will only collect this for those which time allows within the study period and who have completed all previous three data collections. A subset of patients in the intervention arm who complete all assessments will be purposefully selected and invited to take part in a qualitative interview to discuss their experiences.

SWISH STAFF AND ROLES

Two staff (NA and CD) are employed for the duration of the project (May 2014 – Mar 2016). An extra member of staff was appointed for six months from June-Dec 2015.

Nilu Ahmed – Chief Investigator (full time May 2014 – May 2016)

- manage all aspects of the project
- manage the budget
- manage Research Assistants
- ensure timescales are met, and apply for extensions to funders if needed
- ensure cordial working relations with Crisis Resolution Teams in GGH and PPH
- work with Mental Health Services
- ensure ongoing involvement of service users
- create and update Trial Masterfile
- write and update protocol
- develop all study documents (information sheets, letters, consent forms etc)
- be responsible for paperwork to ethics, NHS R&D, NISCHR, HDUHB
- prepare quarterly reports for funders and trial management group
- prepare conference papers and journal articles
- implement WWORTH GCP guidelines for delivering an RCT
- register the study with STU (formerly known as WWORTH)
- develop the intervention
- recruit suitable patients to SWISH
- randomise all patients to either arm of the trial
- deliver the intervention
- update patient information on NHS FACE system

Charlotte Davies (Part Time 0.6 May 2014 –May 2015; 0.8 Jun-Sept 2015; 0.6 Oct 2015-Apr 2016)

- recruit suitable patients to SWISH
- work closely with Crisis Teams and Mental Health Services
- assess suitability of referrals
- conduct baseline assessments
- conduct follow up assessments for all patients at 4 weeks and 12 weeks
- update patient information on NHS FACE system
- maintain and update study patient files
- update CRN files
- be responsible for ordering vouchers and ensuring they are sent to all participants at relevant stages
- conduct a six month follow up of all patients who complete all data collections (if timescale allows)
- present study to relevant audiences
- conduct semi-structured satisfaction interview with 10% of intervention patients
- contribute to reports and papers for SWISH

May –October 2015

- randomise all patients to either arm of the trial
- deliver the intervention

Ashrafunessa Khanom (Full Time Jun 2015- Dec 2016)

- recruit suitable patients to SWISH
- work closely with CRHTs Mental Health Services
- conduct baseline assessments with patients consented
- conduct follow up assessments for all patients at 4 weeks and 12 weeks
- update patient information on NHS FACE system
- maintain and update patient files
- present study to relevant audiences
- contribute to reports and papers for SWISH

Staff Base

The office base is in St David's Park. In addition the staff have access to space with the Crisis Teams in Glangwili General Hospital and Prince Phillips Hospital. Honorary contracts are in place with HDUHB.

Partners and Roles

Hywel Dda University Health Board (HDUHB)

The main partner from HDUHB is Richard Jones, Advanced Nurse Practitioner and Clinical Supervisor for SWISH. RJ has overall managerial responsibility for NA, CD and AK. Attends weekly meetings and provides on call support for SWISH staff (see applicant information for more information)

Crisis Resolution Home Teams (CRHT)

CRHT refer patients they have assessed that they feel are suitable for SWISH. All referrals are assessed independently by SWISH before recruitment to the study. In addition they offer a base for SWISH to access the FACE system to write up patients.

Local Primary Mental Health Support Services (LPMHSS)

SWISH attend the referral meetings on Mondays and Tuesdays at St Brides in St David's Park, Carmarthen, and Cae Bryn at PPH to pick up patients that appear to meet SWISH inclusion criteria. All referrals are assessed independently by SWISH before recruitment to the study.

Community Mental Health Teams (CMHTs)

CMHTs make referrals to SWISH where they identify suitable patients. All referrals are assessed independently by SWISH before recruitment to the study.

Street Triage (ST)

ST make referrals to SWISH where they identify suitable patients. All referrals are assessed independently by SWISH before recruitment to the study.

Swansea Trials Unit (STU)

STU (formerly WWORTH) are providing the randomisation service for SWISH and analysis support. Mihaela Barbu (MB) has developed an online tool to allow off site randomisation. Alan Watkins is Senior Statistician and has developed a Data Analysis Plan which will be delivered by Saiful Islam, statistician at STU.

Bangor University (BU)

Peter Huxley (original PI) moved to BU from January 2015 formally but had been winding down duties significantly from 2014. There is a contracted agreement for payment for PH's contribution in place between SU and BU.

PROTOCOL VERSIONS AND AMENDMENTS

Previous protocol versions are available from the CI Dr. Nilufar Ahmed. All updates versions will be approved by co-applicants and sent for information to REC and HDUHB research division and available to funders. All parties will be informed of all minor and major amendments.

OVERALL TRIAL INFORMATION

BACKGROUND AND RATIONALE

The economic burden of mental ill health accounts for one-fifth of all global disease[1]. The annual cost in Wales has been estimated at £7.5 billion[2]. The cost of deliberate self- harm (DSH) in the UK has been estimated to be £56m in hospital costs alone[3]. Australian research[4] suggested that depression was present in 92% of their DSH cases. In the UK, despite NICE guidelines suggesting all DSH cases should have a psychosocial assessment (PA)[5], only 60% receive PA[6]. No contact with psychiatric services is associated with having no PA in hospital[7]. Evidence about the best form of help for first-episodes of DSH is limited[8]; assertive follow-up may reduce future episodes[9].

The proposed study will provide an early intervention for people who have no contact with psychiatric services but who have harmed themselves, most commonly by self-poisoning[10]. The intervention was developed in Australia[4] where it reduced further episodes and improved various aspects of life quality[11]. The intervention was designed specifically to address psychosocial problems and is based on PA, assertive engagement, brief client-centred psychotherapy and community linkage. Our aim is to see if it can be equally successfully introduced in Wales. The need for research to reduce episodes of self-harm can be demonstrated in terms of societal duty-of-care, by demand on services, and policy relevance. Mental health problems account for 20% of the global burden of disease, a larger share than any other health problem (including cardiovascular diseases and cancers). The Friedli/Parsonage Report[2] estimated the annual cost of mental ill health in Wales to be £7.2billion. This figure included health service costs and lost production.

Deliberate self-harm is the strongest risk factor for future suicide[12]. The risk of suicide increases 50 to 100 times within the first year of an episode compared to the general population[13]. People presenting with all other types of self-harm methods have a similar risk of eventual suicide as those who poisoned themselves, however, self-poisoning preceded 67% of subsequent suicides[10,11]. For hospital treated self-harm the year median suicide proportion is 2%. DSH is one of the most common reasons for admission to A&E departments, but is widely accepted as being poorly managed[14,15,16,17]. NICE guidelines[5] recommend that mental health and risk assessment are conducted in all cases of self-harm; but almost half of patients never have one[6]. Not having any previous DSH episodes reduces the likelihood of a specialist assessment being conducted[7].It has been suggested that 'each episode of DSH is potentially the last episode before death and as such, represents an opportunity to make a life-saving intervention'[18]. It has also been suggested that there is a need for more empathic responses to DSH from professionals, especially in A&E settings[19]. Together for Mental Health[20] - the new mental health strategy for Wales emphasises the need for staff in Emergency Departments to manage people who self-harm 'with empathy' and 'careful risk assessments' (p36)

Improving the mental health and well-being of the people of Wales is a key priority for the Welsh Government (WG), as demonstrated by new legislation in the form of the Mental Health Measure (2010)[21], and the new mental health strategy for Wales – Together for Mental Health (TMH)[20]. This proposed study has direct relevance to the Measure, which emphasises mental health promotion and prevention of mental ill-health through early access to mental health services via primary care, and appropriate assessment, care-planning and re-referral mechanisms for people presenting to secondary care services. It addresses the TMH strategy, which is aimed at promoting better well-being and enhancing potential for economic gains through improved mental well-being (p5). TMH draws upon recent Audit Office reports on Adult Mental Health Services, and Housing Services for People with Mental Health Needs, and recognises that mental health is affected by the life-domains in our quality of life measure: finance, accommodation, safety, health, work and education, family, leisure and social activity. All of these areas can be addressed by the proposed intervention and its proposed outcome measures. The study also relates to Fairer Health Outcomes for All[22], which commits the WG to reduce health inequalities and improve people's mental health.

The proposed study addresses TMH's emphasis on early intervention (p16), treatment based on sound evidence (p8-9; p42), cost-effectiveness (p10) and person-centred approaches (p35). A primary outcome of the proposed study is a reduction in depression scores, depressive symptoms are strongly correlated with self

harm. A secondary outcome is to reduce repeat DSH admissions; one TMH outcome indicator is to reduce inappropriate hospital admissions (p35) and re-admissions (p39).

The study is consistent with the National Action Plan to Reduce Suicide in Wales[23] in that DSH is the most consistent predictor of suicide. The proposed study group are those people who are not actively involved with psychiatric services, but whose actions and/or thoughts have led to them being assessed as high risk for suicide.

TRIAL DESIGN

This is a non-blinded parallel randomised controlled trial

TRIAL OBJECTIVES

Objectives	Outcome measures
Primary Objective To investigate whether the intervention leads to a decrease in BDI-II scores compared to treatment as usual	BDI-II administered at baseline, 4 weeks and 12 weeks to patients in both arms of the trial
Secondary Objectives To investigate whether the intervention leads to an increase in overall wellbeing and social outcomes To investigate whether the intervention leads to a differences in re-admission between the groups	MANSA will be administered at baseline, 4 weeks and 12 weeks to patients in both arms of the trial SAIL are involved to access hospital data to track readmissions and presentations to GP

SAMPLE SIZE

We will recruit 120 patients in total – 60 in each arm of intervention and control. If we are struggling to recruit enough patients, we may oversample to the intervention arm. This will only be done after full discussion with the TMG and with support from STU to ensure the rigour in the randomisation process remains.

EXPECTED DURATION OF TRIAL

The expected duration of the full trial including follow up assessments is 12 months with patient recruitment running for a maximum of 10 months. Six month follow up will only be conducted on those recruited in the first six months of the trial. The end of trial will be the date of the last follow up assessment conducted by the Research Assistant.

SUBSEQUENT OPPORTUNITIES FOR PARTICIPATION

During the course of the study patients who have previously presented at A&E with self harm or been referred to Mental Health Services by their GP and not been recruited to the study (either through being missed, or through not wishing to take part) will be invited to take part in the study again. This is in line with the Australian study where they found that some patients who had initially declined to take part, consented at a subsequent presentation to A+E.

Withdrawal of subjects

Patients have the right of withdrawal at any point during the study, without any obligation to disclose the reason for their withdrawal. We will use any anonymised data we have already collected. Patients may be withdrawn from the study by investigators if during the study their condition changes and they meet any of the exclusion criteria. Patients will not continue with further assessments, but we will use the data we have collected till their withdrawal.

Blinding of Research Assistants

Researchers are not blinded in this study. Initially an attempt was made at blinding, but this proved ineffective. Patients are likely to share which arm they are in with the RA at T2 data collection. It is advisable for the team to be able freely discuss patients, especially if there are concerns about changes in patient presentation or heightened risk. Given time constraints the T2 can be administered by the practitioner during an intervention contact. Previously when NA was conducting the intervention and CD was blinded, intervention meetings would have to be rearranged and the patient would be inconvenienced by accommodating SWISH twice within a matter of days for the 4 week assessments.

Randomisation process

After patients have provided signed consent and completed the baseline assessment they are randomised to either intervention or control by the practitioner using a bespoke online randomisation tool which has been designed for SWISH by STU. The practitioner enters patient's initials, gender and date of birth into the online form, this generates a unique patient identification number. The patient can then be randomised. As long as there is internet access, the process takes less than a minute to complete securely by phone or computer. Those randomised to the intervention will be invited to take part in the first intervention meeting as soon as they feel comfortable to take part. They will be reminded that whilst they have been randomised to the intervention, they do not have to take part in the intervention and can continue with assessments only, or withdraw at any time altogether from the study. Patients will be fully aware of which arm of the trial they are in as the information sheet informs them SWISH is a 4-6 week contact programme or treatment as usual.

We performed an individual randomisation of the patients from study population who met the inclusion-exclusion criteria. Patients are randomised after completion of baseline assessment by the Intervention Practitioner using an online randomisation tool managed by Swansea Trials Unit. The selected patient are randomised with a ratio of 1:1 to intervention and control and used the random number generated from *New Cambridge Statistical Table*[24]

Patient Identification

Patients who meet the inclusion criteria are identified by Mental Health Practitioners and healthcare staff at Glangwili General Hospital (GGH), Prince Phillip Hospital (PPH), Street Triage (ST), Local Primary Mental Health Support Services (LPMHSS), and Community Mental Health Teams (CMHTs) and referred to SWISH. A SWISH team member attends weekly referral meetings to pick up potential patients LPMHSS. Where a suitable patient is identified through ST, CRHT and CMHT base, the team will refer the patient to a SWISH worker who will assess suitability for SWISH. In addition NISCHR CRC have provided research support staff at GGH – Bryan Phillips, a nurse based at GGH checks in at A&E every weekday morning and informs the CI of any self harm patients who have presented overnight.

SWISH staff follow up patient referrals as soon as possible. The Australian study aimed to recruit patients within 72 hours of their presentation. Given multiple sites and part time staff, SWISH will recruit within 5 days

of referral to SWISH. The time elapsed since presentation/referral/recruitment will be documented for analysis purposes.

If SWISH are able to recruit a patient at hospital they conduct the assessment face to face. For those who are discharged (e.g. weekend presentations), or are referred from other services, SWISH conduct a telephone assessment to ensure that patients meet SWISH criteria. At this telephone assessment SWISH incorporate elements from the Pierce-Beck Suicide Intent Scale (currently used in A&E within HDUHB). The questions on the scale are used to guide the conversation only and scores are not recorded for analysis nor are the answers used to determine inclusion/exclusion.

Inclusion criteria:

- person 18 or over who presents to Mental Health Services (either directly at hospital or indirectly through referral) with self-harm and/or suicidal ideation

Mental Health Services are defined as:

- A&E and Crisis Teams at Glangwili Hospital and Prince Phillip Hospital
- Local Primary Mental Health Support Service
- Community Mental Health Team
- Street Triage Team

Exclusion criteria:

Anyone who, following a psychosocial assessment by a registered Mental Health Practitioner, is:

- unable to give informed consent
- so unwell that they have to be admitted to a psychiatric bed
- requires secondary mental health services
- assessed as high risk for violence
- known or assessed to have a severe mental illness and require other services
- is under a current and active care treatment plan with Adult Mental Health Services
- is unable to communicate in English

PATIENT RECRUITMENT AND INFORMED CONSENT

Patients who meet the inclusion criteria are contacted as soon as possible by a SWISH worker who explains the study to them and gives them the opportunity to ask questions. Patients will be fully aware that verbal consent does not oblige them to take part. They will be reminded that they can withdraw from the study at any time before or after signed consent without it affecting their care.

LPMHSS discuss referrals at a weekly meeting where they are allocated to members of the team for telephone assessments. LPMHSS have a 28 day window for this assessment. Waiting for an assessment by LPMHSS could impede SWISH in meeting its recruitment timeframe, so SWISH pick up patients from these meetings whose referrals meet the inclusion criteria. SWISH contact patients by phone and inform them that LPMHSS will be in touch within 28 days, and in the meantime they may be eligible for an additional service that is being trialled. Patient can consent or decline. If a patient consents a note is made on the referral fax that they have been recruited to SWISH by named SWISH worker and to see FACE for details. If the patient declines and has not been assessed by LPMHSS, a note is made on the referral fax to say the patient declined (this will not be recorded on FACE but it will be on SWISH study records).

For patients seen outside of hospital the SWISH worker will arrange a convenient time and place. The first option will always be a healthcare or other public setting, but it is likely that many patients will request a home visit. For a first home visit two SWISH workers will attend for safety and risk assessment reasons.

Access to patient records

It is essential that SWISH staff access patient NHS records to familiarise with patient history and to ensure that the patient does not meet any of the exclusion criteria. As part of the collaborative agreement with HDUHB the SWISH staff are required to update patient files on the NHS FACE system after every contact. The Researchers need to access to patients' telephone numbers and addresses to contact them for intervention and follow up questionnaire assessments, as well as details of patients' GP addresses to send the GPs notification of patients' participation in the research. This information can only be accessed on an NHS Hospital site.

Recording patient data

All SWISH staff have access to the FACE system for recording patient data on to the NHS system. All SWISH records will be recorded under 'primary care' rather than secondary care as patients would ordinarily be referred back to primary care. Charlotte Davies is maintaining an anonymised EXCEL database of patients.

Assessments

All patients will be asked to complete assessments (BDI-II, MANSA and CSRI) at Baseline (before randomisation), 4 weeks and 12 weeks. Those who fall in to the six month period whilst the study is running will be invited to complete a 6 month assessment. The RA will upload the responses onto SPSS for future analysis by the statistician. Data will be checked by STU.

Baseline Assessments

The baseline assessment consists of the BDI-II, MANSA and CSRI. Patients will be asked to complete these questionnaires as soon as possible after they consent. It is expected the patients will complete the questionnaires unaided, with the researchers providing clarity where needed, although some may ask that the questionnaire be read to them; SWISH staff will comply with this request reading out questions and circling the responses given. Researchers will note whether they were required to read out any/all questions, and any questions patients have asked for clarity or elaborated upon while completing the questionnaire pack. Patients are informed that completing the baseline assessment could take up to an hour. We anticipate it will take less than this for most patients, as the questionnaires are relatively brief and require only tick box answers.

Where possible, baseline assessments for those who present directly will be conducted in hospital before discharge. However, where patients are followed up after discharge or for other referrals, baseline assessments will be collected within 72 hours of patient notifying us of their interest. Patients will be given a £10 shopping voucher for the time after completing the baseline assessment.

Follow up assessments

Follow up assessments will be conducted with the same questionnaires (BDI-II, MANSA, CSRI) at 4 weeks and 12 weeks (in line with the timeline adopted by the Australian study). The assessments will be arranged and collected by the Research Assistants. The patients are expected to complete the questionnaires without assistance, but may ask for clarity.

Patient are given no incentive at the 4 week assessment, but those who complete the third assessment at 12 weeks will be given a £20 voucher for their time. If there is difficulty in getting patients to commit to a 4 week assessment a £10 voucher can be offered for the 4 week assessment and the final £10 at the 12 week assessment.

Trial evaluation

Patients who have completed all assessments and the intervention, will be invited to complete a short evaluation form of their experience of the study with the RA. There will be an opportunity to write in further comments or discuss with the RA who will record them verbatim. This will be be helpful in providing more detailed experiences of the service and help to develop it further for future trials.

Both intervention and control patients will be asked about their experience. This will help ascertain whether control patients found the contact from the researcher beneficial. The process of completing questionnaires can force reflection and discussion of feelings with the researcher. This means our control group is not wholly indicative of Treatment as Usual group who do not get such an opportunities to reflect on their feelings.

Six month follow up

The Australian study implemented a six month follow up for patients who had completed assessments at baseline, 4 weeks and 12 weeks. This is a short feasibility study and it is unlikely we will have time to follow up all patients. Where we have time, we will invite patients to a six month follow up to complete the assessments (BDI, MANSA and CSRI) again.

THE INTERVENTION

The intervention is a 4-6 week contact programme which is a mix of face-to-face and telephone contact. It deliberately steers away from being a psychological or medical service; rather it is based on linking individuals into social support networks and encouraging access to, and engagement with, relevant services. An awareness of local third sector services is key to the role. The role of practitioner is one that can be delivered by a skilled individual who has experience of working with people with mental health issues. The practitioners delivering the intervention in this trial have worked in mental health services but are not registered mental health practitioners. They have experience of working in Carmarthenshire within mental health services and/or developing mental health services for vulnerable populations. By not requiring practitioners to hold registrations, the intervention is more cost effective to deliver, as it relies on locality-based training and awareness. The practitioners receive clinical supervision from an Advanced Nurse Practitioner in mental health services. Formal supervision is once a fortnight or more depending on requirements; the supervisor is available at all times on the phone for immediate questions. The intervention encourages individuals to link with local services. In this trial some of the agencies patients are linked into include Men's Shed projects, adult education courses, knitting groups and volunteering services; as well as services supporting individuals with drug and alcohol issues and domestic abuse. The choice of service is decided alongside the patient based on the type of support and engagement they would like. The intervention primarily focuses on the social dimensions of a person's life; the medical and psychological needs of the patient will have been assessed prior to the patient's referral to SWISH. If at any time during the intervention the practitioner is concerned that these needs may be escalating and require specialised support, they will be referred accordingly; and SWISH will continue to support the patient for the duration of the intervention, or until they meet the exclusion criteria and are engaged with relevant support services.

The first patient-practitioner contact is as soon as possible after baseline has been collected by a research assistant. At the first meeting the patient is encouraged to discuss recent events and explore the reasons which they feel led to their current situation. This meeting typically lasts about an hour. The practitioner works with the patient to identify the main social issues they feel precipitated this and discusses relevant agencies

that may be able to offer support and information. A plan of action is then worked out with the patient where the patient is given suggestions for services that they can link in with. Treatment as usual for patients with low or no mental health history and risk who present to the hospital Emergency Department is usually referral back to GP; although some might be signposted to services in the community usually by way of leaflets provided. This intervention goes beyond signposting to assertively link the patient with relevant services to embed them within a supportive network at a time of emergency and vulnerability to try and ameliorate the negative impact of the self harm episode. The 'assertive community linkage' is the basis for the intervention. It encourages patients to contact relevant community agencies who can provide specialised support and establish a supportive resource to help manage future periods of stress.

Subsequent follow up contacts are a mix of face-to-face and telephone contacts depending on agreement and discussion with patient. Patients are seen at a location that is convenient to them, this includes home visits, however as part of the community linkage patients are encouraged to engage outside of the home and so meetings are held in local spaces including GP surgeries, coffee shops and arts centres. Details of all contacts are logged on the FACE electronic recording system used by Hywel Dda University Health Board as their health care notes recoding system. The number and nature (face to face or telephone) and length of contacts vary depending on patient need and are mutually decided between patient and practitioner. The minimum number is four and the maximum is usually six, with the first and final contact always being face to face. As this is a feasibility study we have been flexible with the final number of sessions to accommodate patients who may be waiting for another service. In this situation SWISH provides support until they are engaged with another provider. This has resulted in up to eight sessions in three cases.

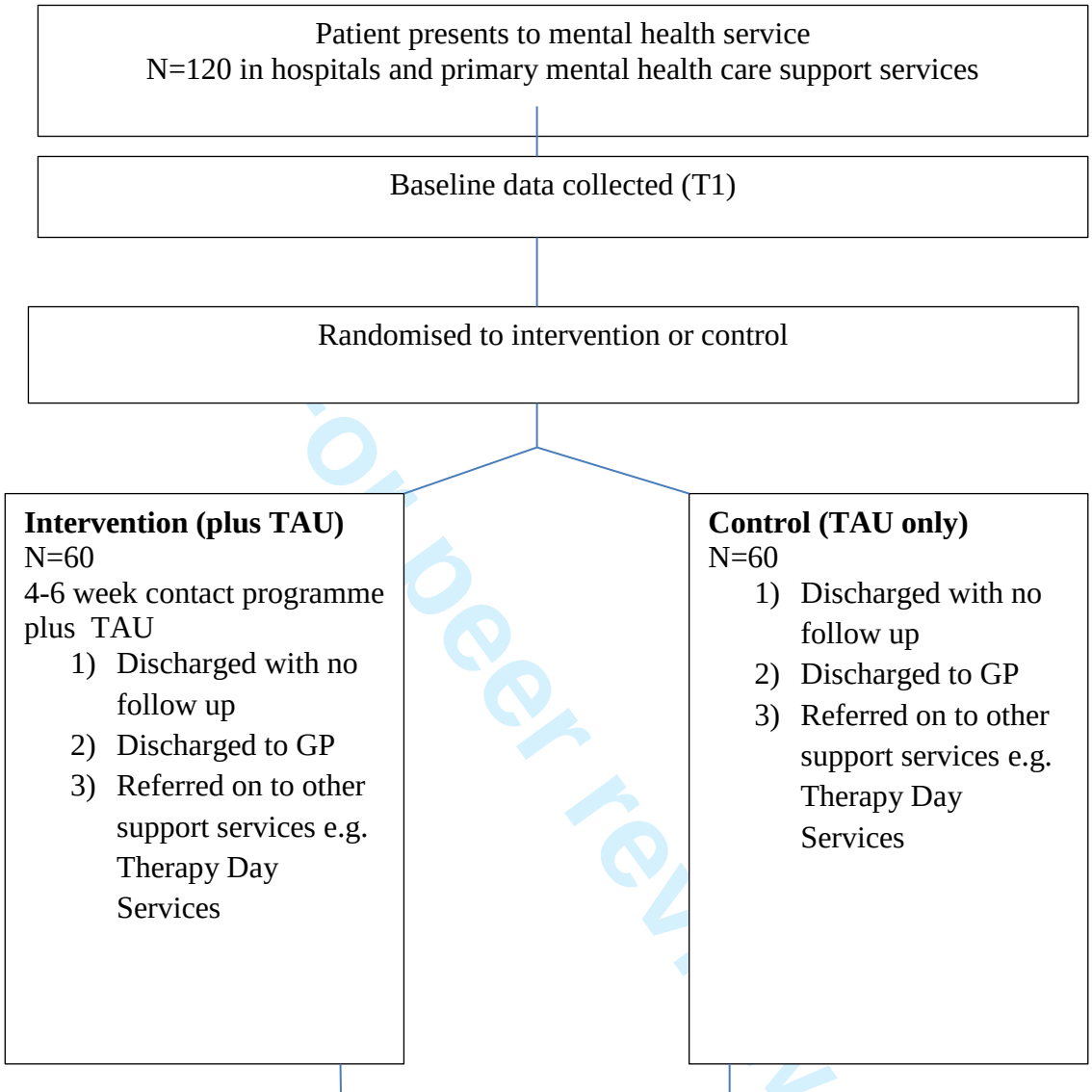
This is an important feature of the intervention where as well as providing a stand-alone service linking individuals to community services; it acts as a bridging service for patients. Patients referred to Local Primary Mental Health Support Services and those who have been referred to other (non-secondary) mental health support services such as psychological therapy services typically face a 4-8 week wait for assessment. The intervention provides a point of regular contact and support during this waiting this period.

For many patients the required support may be much simpler and they require just regular contact and the opportunity to discuss their feelings. The intervention is flexible to meet the needs of the patient and accommodates this. Not all individuals have the time, capacity or emotional energy to pursue other services and activities. Carmarthenshire is largely a rural county and access to services can be limited for some. SWISH is a flexible service and the intervention support ranges from providing talking support to signposting and where appropriate, referrals to community services. Its constancy lies in regular contact with the patient and providing social support.

SWISH is not a replacement service for support services already in place. It encourages patients to engage with existing services. As such, as long as patients are not receiving support from secondary mental health services (an exclusion criteria based on higher support needs of secondary mental health service users); there is contraindication to involvement with SWISH.

Patients are eligible for SWISH support unless they meet the exclusion criteria. All such cases will be referred to the clinical supervisor who will ensure appropriate support is in place for the patient before withdrawal from the study.

Study Chart



Translation of patient information materials

Patient information will be available in English and Welsh. However at this point, for a feasibility study it is simply not feasible to conduct the study in any language other than English, and any patients who present with other languages will be excluded from the study. We have discussed with Chris Tattersall, Head of Research at HDUHB, who assured us that for a feasibility study, only English would be sufficient as the number of patients presenting with Welsh language only, or Welsh language preference was very low across the research site (telephone conversation 23/06/2014).

Safety procedures

Researchers

SWISH will only recruit patients who are deemed medically fit for discharge. The SWISH team will, where available, access patient notes to check for history of presentation to the service and any risks previously noted relating to safety and violence issues. Any patient who has a record of violence will be excluded. This is in line with the Australian study where the intervention is directed at low level need and risk patients. For first time home visits there will be two staff. Both Research Assistants will attend home visits that require double handed calls. For lone visits, SWISH staff will text another member of the SWISH team with the Patient ID of the patient they are visiting before they visit and text again after visit. It will not always be possible to text at point of arrival and departure from the visit as Carmarthen is a very rural county and many patients will live in areas with no mobile phone reception.

Patients will be encouraged to attend hospital, GP surgery or an agreed location such as community mental health team bases for follow up meetings (intervention and assessments); but there is a risk of losing too many patients if home visits are not offered. Currently the crisis teams within HDUHB, offer a home visit service. The teams will be consulted for advice on new patients referred to SWISH, and will be informed when a SWISH worker conducts a home visit.

Patients

Talking about the events which led to the presentation in hospital, and about issues which may be affecting individuals can be upsetting. The SWISH team are trained mental health workers experienced in working with people with mental health issues. They will offer to suspend, postpone or end the session if the patient is feeling uncomfortable. They will reiterate that the patient can withdraw from the study entirely if they feel their involvement in the study is affecting their wellbeing. SWISH workers will also offer to refer them to other services if the patient would like more involved support and services. Where the SWISH workers feel a patient is at risk and their health is deteriorating, they will inform the patient of their concern and contact the GP and discuss with clinical supervisor Richard Jones for the best route of care.

Reporting adverse events

All adverse events will be reported to the Clinical Supervisor and CI immediately and documented for study reference. Appropriate responses will be made based on nature of event.

Data Collection Tools

The assessments are all standardised forms (BDI-II, MANSA, CSRI) and have been compiled in to an assessment pack for this study.

The Pierce-Beck Suicide Intent Scale is a standardised form used across A&E in HDUHB. SWISH are not using this as a data collection tool, but as a source of questions for assessments. No standardised data from this scale are recorded.

The intervention case report form is an original data collection tool and will be used to guide the areas of exploration in the intervention and record verbatim the conversation with patients. It incorporates the Mental State Exam which is used by the crisis teams as part of their assessments. All information collected on the case report form will be typed up and saved on to FACE. The handwritten case forms will only have the patient ID number as identifier and be stored in a locked filing cabinet on university premises. This will be a separate filing cabinet to the ones containing the assessments.

DATA MANAGEMENT

The CI acts as custodian for the trial data. The following guidelines will be strictly adhered to:

All personal identification documents (e.g. referral forms, signed consent forms) will remain on the NHS site and stored securely in the CRHT offices where the Researchers update NHS FACE files. Paper versions of data collection forms will not contain any patient identifiers and will not be held together with patient identifiers. All completed assessments will be labelled with patient ID numbers only and will be stored in lockable separate filing cabinets, with the intervention case report forms locked in a separate cabinet. The data will be held in a locked room, in an ID card accessed building with reception staff at the front desk.

Electronic data containing patient identifiers, will be held on password protected databases with restricted access to both:

- one with only identifiers and a study ID ONLY and
- one with all relevant study data and study ID only to prevent patient data being identifiable.

Data security protocols for trials will comply with the principles of data confidentiality set out in the Data Protection Act 1998 and MRC's guidelines Personal Information in Medical Research, both of which inform the STU guidelines which this study conforms to.

All project data will be stored on password secured files. We will ensure systems of record keeping and database management to prevent the loss, missing or unreadable information that compromises future data analysis. All paper documents will be kept for the required period of data storage in a card access room in a locked building.

DATA RETENTION AFTER THE STUDY

All hard copies will be shredded within 6 months of the end of the study, and all data files will be kept in accordance with STU guidelines. The co-applicants will have access to the data on request for further outputs.

REPORTING

The CI will submit quarterly reports to the funder, HDUHB, and Trial Management Group and annual report to the ethics committee. The final study report (due Summer 2016) will be circulated to the funder, sponsor, and HDUHB before wider dissemination practices.

ANALYSIS

The between group differences in mean scores will be analysed. The primary outcomes is the BDI-II score. The main hypothesis is there will be significantly greater change in BDI scores in the intervention group than the control. The study is powered to detect a ten point difference in the BDI score between the arms of the trial at 12 week follow up as it has been shown to correspond to a clinically recognised moderately important difference in outcome. A difference of 20 points represents and large clinical difference in outcome, but it is unlikely that average changes of such magnitude will be identified in this group in a short 12 week follow up. Saiful Islam, trial statistician will lead the analysis.

Health Economics

Health service resource use in primary care, secondary care and the community is collected using the CSRI from participants in both arms of the trial at baseline, 4 weeks, 12 weeks and 6 months. Questions will relate to all health service contacts (hospital appointments, hospital stays, GP contacts, visiting nurse appointments, etc.) and prescription medicines dispensed during the trial period. Patient recall has been shown to be a valid method for collecting health service resource use data over this period (and, as clinical records are often fragmented, and sometimes unavailable, across different parts of the health service) patient-reported data is likely to remain more readily available and less costly to collect for research purposes[25]. A descriptive analysis of CSRI data, along with estimates of the cost of providing the intervention, will provide a comparison of participant resource use between intervention and control groups, and will provide indicators of the main resource use (and associated costs) drivers of those receiving the intervention.

The CSRI data will be summarised and presented descriptively. The resources utilised and associated costs will be summarised. The costs of the intervention will be estimated. These data will be used to compare the costs of the intervention and usual care and to inform the calculation of incremental costs. The sources of costs will be fully referenced to aid transparency of the analysis. Where possible, published unit costs will be used (e.g. PSSRU Costs of Health and Social Care, British National Formulary, NHS reference costs) using the most recent published sources - 2014/15. Costs (mean and SD and/or 95% confidence intervals or non-parametric equivalent (median and IQRs) will be presented.

SAIL

The project is registered with the Secure Anonymised Information linkage (SAIL) database to allow us to follow up patients use of health services after the trial has ended. This is an important registration as it will allow us to be able to gather information on the long term use of services by patients and compare service use and re-presentations to A&E by intervention and control patients.

PUBLICATION POLICY

There will be at least four academic papers published.

- A protocol paper
- A systematic review paper on short interventions in self harm
- 2x findings papers

We follow BMJ guidelines for authorship and contribution:

- 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

As per BMJ requirements ***ALL*** *four of the above points must be met for authorship*. Contributions will be acknowledged at the end of the paper as per BMJ guidelines.

Ethics and Regulatory Approvals

The study is conducted in compliance with the principles of Good Clinical Practice (GCP) and in accordance with guidelines from Swansea Trials Unit (STU). The study was been approved by the host institution, REC 6 and NHS R&D before the study commenced. A substantial amendment was submitted to REC 6 November 2014 and approved (this pertained to the change of PI from Peter Huxley to Nilufar Ahmed; and all parties were informed) and a minor amendment was approved in May 2015. The CI will ensure any amendments will be agreed by Trial Management Group and submitted to REC and host institution for approval before implementation.

Trial Management Group

The core Trial Management Group is made up of the Nilufar Ahmed (Chief Investigator), Mihaela Barbu (STU), Lily Bidmead (Service User); Charlotte Davies (Research Assistant); Angie Darlington (West Wales Action for Mental Health); Peter Huxley (co-applicant, Bangor University); Saiful Islam (STU); Ann John (co-applicant, College of Medicine); Richard Jones (HDUHB partner and Clinical Supervisor); Ashrafunessa Khanom (Research Assistant) Penny Llewelyn (Service User). This group meets quarterly or more often if needed. Also invited to attend these meetings are co-applicants and as relevant, HDUHB staff including Crisis Team Managers, Research and Development Manager and Clinical Managers. Additionally STU staff attend as required to advise on specific matters as they arise. NA also circulates monthly bulletins to the TMG to keep them informed of progress.

Insurance and Indemnity

The Researchers hold honorary contracts with HDHB and the NHS provides indemnity for NHS sites, for all non-NHS sites, indemnity is provided by the sponsor, Swansea University.

Signatures

16 November 2015

Chief Investigator
Nilufar Ahmed

Date

REFERENCES

1 Ngui EM, Khasakhala L, Ndetei, D, Roberts LW Mental Disorders, health inequalities and ethics: A global perspective. Int. Rev. Psychiatry 2010; (22(3) 235-244.

2 Friedli L, Parsonage M. Promoting mental health and preventing mental illness: the economic case for investment in Wales. Cardiff: All Wales Mental Health Promotion Network, 2009.

3 Sinclair JMA, Gray A, Rivero-Arias et al . Healthcare and social services resource use and costs of self-harm patients. Soc Psychiatry Psychiatr Epidemiol 2011; 46:263–271.

4 Joubert L, Patrakis M, Cementon E. Suicide attempt presentations at the emergency department: outcomes from a pilot study examining precipitating factors in deliberate self-harm and issues in primary care physician management. Social Work Health Care 2012; 51(1)66-76.

5 National Institute for Health and Clinical Excellence. Self-harm: longer term management (Clinical Guideline CG133) 2011.

6 Gunnell D, Bennewith O. Peters TJ et al. The epidemiology and management of self-harm among adults in England . Journal of Public Health 2005; 27 (1) :67-73.

7 Bennewith O, Peters TJ, Hawton K et al. Factors associated with the non-assessment of self-harm patients attending an Accident and Emergency Department: results of a national study. J.Affect. Disord. 2005;89(1-3)91-7.

8 Leitner M, Barr W, Hobby L. Effectiveness of interventions to prevent suicide and suicidal behaviour: a systematic review. Health and Community Care Research Unit, Liverpool University and Scottish Government Social Research.

9 McNiel DE, Binder DL. The impact of hospitalization on clinical assessments of suicide risk. Psychiatric Services1997:, 48, 204 - 208.

10 Bergen H, Hawton K, Waters K et al. How do methods of non-fatal self-harm relate to eventual suicide?. J. Affect Disord 2012; 136:526-533.

11 Bergen H, Hawton K, Kapur N, et al. Shared characteristics of suicides and other unnatural deaths following non-fatal self-harm? A multicentre study of risk factors. Psychol Med 2012; 42: 727– 41

12 Petrakis M, Joubert L. Suicide prevention through a social work model of assertive brief psychotherapy and community linkage: use of the Manchester Short Assessment of Quality of Life (MANSA). Project report : Monash University and the University of Melbourne Australia, 2012.

13 Hawton K, Harris L, Hall S et al. Deliberate self-harm in Oxford 1990-2000. Psych. Med. 2003;33:987-995.

14 Owen D, Horrocks J, House A. Fatal and non-fatal repetition of self-harm. Systematic review. Br.J. Psychiatry 2002; 181:193-9.

15 Kapur N, House A, Dodgson K, et al. Management and costs of deliberate self-poisoning in the general hospital: A multi-centre study. Journal of Mental Health 2002; 11(2):223-230.

16 Gunnell D, Bennewith O, Peters TJ et al The epidemiology and management of self-harm amongst adults in England. J. Public Health (Oxf) 2005; 27(1)67-73.

17 Bennewith O, Gunnell D, Peters T, et al. Variations in the hospital management of self harm in adults in England: observational study. British Medical Journal 2004; 328(7448): 1108-9.

18 John A. Commentary on Bergen et al. Evidence Based Mental Health 2012:15 101.

19 Long M, Manktelow R. Tracey A. We are all in this together: working towards a holistic understanding of self-harm. J. Psychiatr. Ment. Health Nursing 2012; Epub Mar 7.

20 Together for Mental Health (TMH): A strategy for Mental Health and Well-being in Wales. Welsh Government, 2012.

21 WAG (2010) The Mental Health (Wales) Measure. Welsh Assembly Government, Cardiff.

22 WAG (2011). Fairer Health Outcomes for All: Reducing Inequities in Health. Strategic Action Plan. Welsh Assembly Government, Cardiff.

23 WAG (2008) Talk to me: A National Action Plan to reduce Suicide and Self Harm in Wales 2008-13. Welsh Assembly Government, Cardiff.

23 Haney EM, O'Neil ME, Carson S, Low A, Peterson K,Denneson LM, Oleksiewicz C, and Kansagara D. Suicide Risk Factors and Risk Assessment Tools: A Systematic Review. VA-ESP Project #05-225; 2012

24. Lindley, D. V., & Scott, W. F. (1984). New Cambridge Statistical Tables Cambridge

25. . Ridyard, C. & Hughes, D. (2013) Review and the use of resource instruments based on patient recall in relation to other methods pf resource use estimation. *Trials*, 14, 1-1

SPIRIT
STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number of manuscript
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	1, 11
	2b	All items from the World Health Organization Trial Registration Data Set	N/A
Protocol version	3	Date and version identifier	N/A
Funding	4	Sources and types of financial, material, and other support	10
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1
	5b	Name and contact information for the trial sponsor	11
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	N/A
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	9
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each	2-3

		intervention	
	6b	Explanation for choice of comparators	3
Objectives	7	Specific objectives or hypotheses	3
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	3
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	3
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	4
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	4
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	5
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	N/A
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	6
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	3,9
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	8
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	4
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	N/A
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is	4

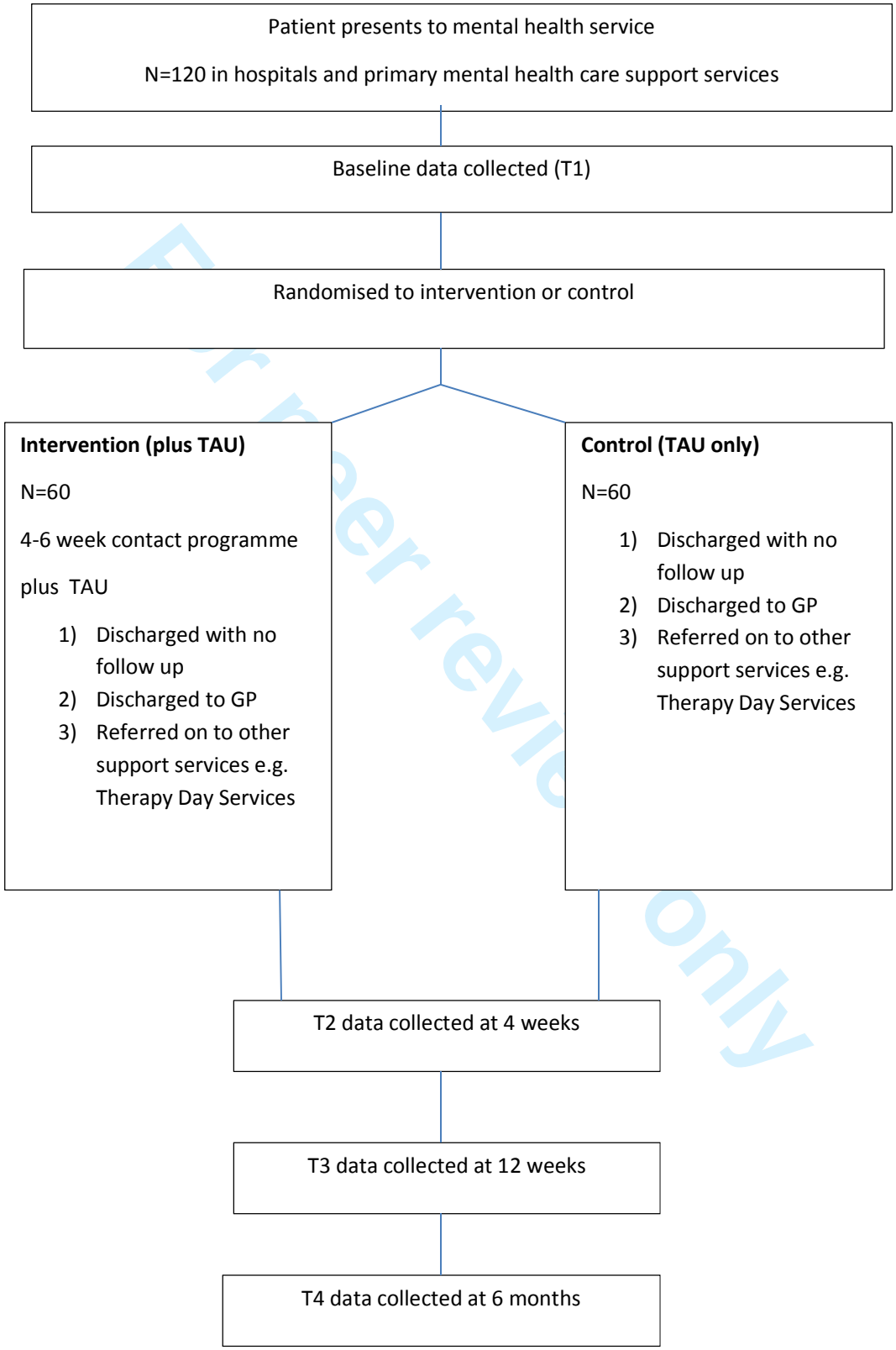
		unavailable to those who enrol participants or assign interventions	
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	4
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	4
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	7
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	N/A
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	6
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	4
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	9
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	9 Contact statistician for more information
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	Contact statistician
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	Contact statistician
Methods: Monitoring			

Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	This is a feasibility study so no formal DMC in place,. However Swansea Trials Unit are managing the data and data is collected in accordance with their regulations
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	N/A
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	N/A
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	None in place formally as this is a feasibility study, but the sponsor has its internal audit process that the trial is subject to.
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	1
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	N/A
Consent or	26a	Who will obtain informed consent or assent from potential trial participants or authorised	3

assent		surrogates, and how (see Item 32)	
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	10
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	N/A
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	N/A
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N/A
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	N/A
	31b	Authorship eligibility guidelines and any intended use of professional writers	N/A
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	N/A
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	attached separately/available from CI
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

Recruitment chart CONSORT statement (NB this chart is included in main document)



BMJ Open

Investigating the feasibility of a social support intervention in self harm and suicidal behaviour: A protocol for a randomised controlled trial delivering a Social Work Intervention following Self Harm (SWISH)

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2016-012043.R1
Article Type:	Protocol
Date Submitted by the Author:	08-Jun-2016
Complete List of Authors:	Ahmed, Nilufar; Swansea University College of Human and Health Sciences, Public Health, Policy and Social Sciences Jones, Richard; Hywel Dda Health Board John, Ann; Swansea University, Farr Institute Islam, Saiful; Swansea University, College of Medicine Anderson, Pippa; Swansea University, Centre for Health Economics Huxley, Peter; Bangor University
Primary Subject Heading:	Mental health
Secondary Subject Heading:	Health services research, Mental health
Keywords:	randomised controlled trial, self harm, intervention, depression, social support, suicide prevention

Investigating the feasibility of a social support intervention in self harm and suicidal behaviour: A protocol for a randomised controlled trial delivering a Social Work Intervention following Self Harm (SWISH)

Nilufar Ahmed*[1], Richard Jones[2], Ann John[1], Saiful Islam[1], Pippa Anderson[1], Peter Huxley[3]

Abstract

Introduction: Self harm is a strong predictor for suicide. Risks for repeat behaviour are heightened in the aftermath of an index episode. There is no consensus on the most effective type of intervention to reduce repetition. Treatment options for patients who do not require secondary mental health services include: no support, discharge to General Practitioner, or referral to primary care mental health support services. The aim of this study is to assess whether it is feasible to deliver a social intervention after an episode and whether this can reduce depressive symptoms and increase sense of wellbeing for patients who self harm.

Methods: This is a non-blinded parallel group randomised clinical trial. One hundred and twenty patients presenting with self harm and/or suicidal ideation to mental health services over a twelve month period who are not referred to secondary services will be randomised to either intervention plus treatment as usual (TAU), or control (TAU only). Patients are assessed at baseline, 4 weeks and 12 weeks with standardised measures to collect data on depression, wellbeing, and service use. Primary outcome is depression scores; secondary outcomes are wellbeing scores and use of services. The findings will indicate whether a rapid response social intervention is feasible and can reduce depression and increase wellbeing among patients who self harm and do not require secondary services.

Ethics and dissemination: Ethical approval was granted by the UK National Health Service (NHS) Ethics Committee process (REC 6: 14/WA/0074). The findings of the trial will be disseminated through presentations to the participating Health Board and partners, peer-reviewed journals, national and international conferences.

Trial registration: The trial is registered with the International Standard Randomised Controlled Trial Network (ISRCTN 76914248); and UK Clinical Research Network (16229)

Keywords: Randomised controlled trial, Self Harm, Suicide, Intervention, Social wellbeing, Social support, Social networks, Depression

*Corresponding Author:
Dr Nilufar Ahmed
27 Haldane Building
College of Human and Health Sciences
Swansea University, Singleton Park, Swansea, SA2 8PP
01792 602819
n.ahmed@swansea.ac.uk

[1]Swansea University
[2]Hywel Dda University Health Board
[3]Bangor University

Strengths and limitations of the study

- Development of an intervention for people who have little or no support following self harm.
- Focus on social issues problems that are present in the person's life
- A cost-effective intervention that can work alongside existing services, supporting patients during a vulnerable time and keeping them engaged whilst they are awaiting assessment from other services.
- Strong retention rate for trial
- Data linkage for long term follow up
- Social linkage relies on access to services and transport that can inhibit those without means and access
- Unblinded trial

Background

Self-harm is the strongest risk factor for future suicide[1] resulting in over 200,000 hospital presentations annually in England and Wales[2, 3]. Self harm is associated with high personal, social and medical costs[4]. Repetition is common, with between 15-25% re-presenting to the same hospital within a year of the index episode[5]. The highest risk of repeat self harm is within 3-6 months after the index episode[6] with the risk for suicide in the year following self harm almost 50 times higher than in the general population[7].

There have been numerous interventions attempting to reduce self harm and suicidal behaviour. These vary significantly in content, and no single type of intervention has been found to deliver consistent results. Depressive symptoms are prevalent amongst those with self harm and suicidal ideation[8] and suicidal ideation is strongly linked with progression to suicide attempt[9]. Due to the strong link between a mental health condition and self harm[10], the majority of interventions targeted at individuals who self harm are based on psychological and medical approaches[11]. A mental health condition in itself does not mean self harm will always be present; many people with a mental health diagnosis do not self harm or have suicidal thoughts[12,13]; and not all of those who present with self harm have, or are diagnosed with, a psychological condition. Self harm may be a response to distress resulting from social factors[14]. For such patients, the lack of medical or psychological care needs often results in receiving little or no support from health care services, with signposting to community services or discharge to General Practitioner (GP) being the main course of management. Supporting individuals to deal with stressors and enabling them to better manage stressors may help alleviate their impact and thus reduce rates of self harm as a response to ongoing or repeated stress.

Whilst NICE guidelines explicitly state that patients who present with self harm should receive a psychosocial assessment[15], this is often not routinely offered[16,] and many patients who present to the emergency department with self harm are discharged without any assessment[17], despite evidence that psychosocial assessment is associated with lower risk of repetition[18]. Presentations to hospital tend to prioritise risk factors to determine medical needs, admission, referral, or discharge, above psychosocial needs. A lack of such exploration leaves much of the psychological impact of social situations under examined. Studies report that as many as 70% of self harm episodes are triggered by interpersonal problems[19]. Whilst addressing immediate psychological and medical needs are vital, a lack of exploration of the social milieu of the patient may miss important factors

that might have been precipitous in the self harm behaviour and therefore may be a recurring antecedent for self harm. It is known that most patients who present with self harm have numerous social and interpersonal problems which catalyse self harm behaviour[20].

The importance of recognising and responding to social factors in self harm and suicide prevention has been described in the literature[21]. There is global evidence of significant increases in suicide rates following economic recession[22] with unemployment being strongly linked with suicide for men and women[21]. Research has also linked an elevated risk of suicide with isolation and a lack of social integration[23].

There is little effective primary care prevention for patients who self harm either as a first episode or repeatedly[24]. Numerous interventions, with varying content have been trialled . Positive outcomes in reducing self harm have been reported for non-pharmacological interventions such as problem-solving therapy[25] and provision of an emergency access card[26]. Findings from contact interventions vary, with some reporting long term positive impacts[27,28,29,30]. Such interventions offer a cost-effective way of supporting individuals by reducing a sense of isolation and increasing a sense of social connectedness; it has been argued that perceived connectedness can reduce suicidal ideation[30]. An elevated sense of support may encourage help seeking at times of crisis[30]. Reviews of contact-based interventions (e.g. postcards, crisis cards, telephone calls) after admission to hospital found inconsistent results across studies and concluded more research is needed[31,32] .

There is a need for further evidence for the effectiveness of social interventions. This study draws on findings from studies which find increasing social support can support those who self harm and reduce suicide rates[27]. An Australian study[33] reported a social intervention focussing on connecting individuals to relevant and available support led to a reduction in depression scores and an increase in wellbeing. This study is designed in a similar way to offer a brief non-psychological and non-medical intervention delivered by trained practitioners.

The aim of this study is to assess whether a social intervention is beneficial for patients who present with self harm and/or suicidal ideation but are not referred to secondary services. The intervention focuses on social factors; it assists in linking individuals to services that can help with social problems including financial issues, housing, relationship difficulties, employment, literacy etc. and also provides a source of social contact at a vulnerable time for those who are isolated. The intervention is flexible to meet the needs of the patient without requiring them to engage with services if they are not ready. It goes beyond signposting with assertively linking the individual to relevant support agencies (e.g. community organisations) that already exist. By doing so, the individual becomes embedded in to a support network which they can draw on at future times of stress. The primary outcome measure is the Beck Depression Inventory (BDI-II)[34], measuring depressive symptoms as depression is a strong predictor of self harm and suicide[35] . Secondary outcomes assess whether a social intervention leads to overall increase in wellbeing, as measured by the Manchester Short Assessment of Quality of Life (MANSA)[36]; and whether the intervention reduces rates of representation to mental health services as measured by the Client Service Receipt Inventory (CSRI)[37] an adaptable tool commonly used to measure service use and further follow up data collection on service use. The project is registered with the Secure Anonymised Information linkage (SAIL) database[38,39] to collect long term data on hospital and primary care presentations for patients for the year preceding and the year following the intervention to record instances of self harm and suicidal ideation prior to and following the intervention. This will provide information on the long term use of services by patients and compare service use and re-presentations to mental health services. SAIL will collect data on patients including the number of presentations to hospital and General Practitioner and reason for attendance. The data will be collected from January 2014-March 2017.

METHOD

Design and setting

This is a randomised controlled trial (RCT) conducted by Swansea University in partnership with Hywel Dda University Health Board (HDUHB) running between January 2015-March 2016 in Carmarthenshire, West Wales. The trial delivers a brief contact intervention to patients over 18 who present to Mental Health Services (defined as hospital Emergency Department and Local Primary Mental Health Support Services) who are assessed to be low risk, and would ordinarily be referred back to primary care and/or community services. Patients who require admission or crisis intervention are excluded from SWISH and referred to appropriate services. Patients are randomised to the intervention or control group. The intervention is a 4-6 week programme of face-to-face and phone call contact tailored to meet the needs of the individual in addition to Treatment As Usual (TAU) which ranges from discharge with no further support, signposting via leaflets to community organisations, or referral to primary care for ongoing care. The control arm is just Treatment As Usual.. The full duration of patient participation is 12 weeks with assessments collecting standardised measures for depression, wellbeing, and service use conducted for all patients at baseline, 4 weeks and 12 weeks. Where possible a 6 month follow up using the same measures will be sought (see Figure 1).

Study population

Patients who present to Mental Health Services (either directly to hospital, or indirectly through referral from General Practitioner to Local Primary Mental Health Support Services) with self harm and/or suicidal ideation are assessed by Mental Health Practitioners at these sites and those thought suitable for SWISH are referred to SWISH in addition to their treatment as usual. A SWISH worker conducts a further eligibility test based on inclusion and exclusion criteria before inviting a patient who meets the requirements to participate. Patients are given a study information leaflet and time to consider whether they would like to take part. Written consent is obtained by the research assistant prior to baseline data collection. Once baseline data has been collected patients are randomly assigned to either intervention or control.

Inclusion criteria:

Person 18 or over who presents to Mental Health Services with self-harm and/or suicidal ideation and is assessed by a Mental Health Practitioner at these sites to not require secondary mental health services and be suitable for SWISH

Exclusion criteria:

Anyone who following assessment by a Mental Health Practitioner, is:

- unable to give informed consent
- requires admission to a mental health inpatient unit
- requires secondary mental health services
- assessed as high risk for violence
- known or assessed to have a severe mental illness and require other services
- is under a current and active care and treatment plan with Adult Mental Health Services
- is unable to communicate in English

At any point if a recruited patient meets any of the exclusion criteria they are withdrawn from the study, but their anonymised data will be retained for analysis.

Power and sample size

The power analysis is based on the primary outcome measure, BDI-II score. Based on published reviews and papers, a five to ten percent change in the BDI-II score represents a clinically important difference and the standard deviation varies between 6 to 10 [40,41,42] which provides an effect size of approximately 0.53. To detect a five to ten point difference in the BDI mean score between intervention and the control conditions, with 80% power requires a sample size of 120 (60 in each arm of the trial).

As this study is assessing feasibility for a full trial of a new intervention, we cannot anticipate the attrition rate, but will use the attrition at 6 and 12 weeks to inform the full trial. For the same reason there are no stopping guidelines, except the complete failure to recruit to the required sample size.

Randomisation

We performed an individual randomisation of the patients from study population who met the inclusion criteria As this is a feasibility study we did not use any stratification for randomisation (e.g. stratify between ideators and self harmers). We will be looking at differences during analysis, and should there any significant differences we intend to incorporate stratification in the future full trial. Patients are randomised after completion of baseline assessment by the Intervention Practitioner using an online randomisation tool managed by Swansea Trials Unit. The selected patient are randomised with a ratio of 1:1 to intervention and control and used the random number generated from *New Cambridge Statistical Table*[43].

Intervention

The intervention is a 4-6 week contact programme which is a mix of face-to-face and telephone contact. It deliberately steers away from being a psychological or medical service; rather it is based on linking individuals into social support networks and encouraging access to, and engagement with, relevant services. It is an additional, rather than alternative service for support services already in place. It encourages patients to engage with existing services. As such, as long as patients are not receiving support from secondary mental health services (an exclusion criteria based on higher support needs of secondary mental health service users); there is no contraindication to involvement with SWISH.

An awareness of local third sector services is key to the role of practitioner. The intervention can be delivered by a skilled individual who has experience of working with people with mental health issues. The practitioners delivering the intervention in this trial have worked in mental health services but are not registered mental health practitioners. They have experience of working in Carmarthenshire within mental health services and/or developing mental health services for vulnerable populations. By not requiring practitioners to hold registrations, the intervention is more cost effective to deliver as it relies on locality-based training and awareness. The practitioners receive received training on mental health service delivery in Carmarthenshire from an Advanced Nurse Practitioner in mental health services. Formal clinical supervision with the Advanced Nurse Practitioner is once a fortnight or more depending on requirements; the supervisor is available at all times on the phone for immediate questions, and monitors the delivery of the intervention and patient contact. The intervention encourages individuals to link with local services. In this trial some of the agencies patients are linked into include Men's Shed projects, adult education courses, knitting groups and volunteering services; as well as services supporting individuals with drug and alcohol issues and domestic abuse. The choice of service is decided alongside the patient based on the type of support and engagement they would like. The intervention primarily focuses on the

social dimensions of a person's life; the medical and psychological needs of the patient will have been assessed prior to the patient's referral to SWISH. If at any time during the intervention the practitioner is concerned that these needs may be escalating and require specialised support, this will be discussed with the clinical supervisor and they will be referred accordingly; and SWISH will continue to support the patient for the duration of the intervention, or until they meet the exclusion criteria and are engaged with relevant support services.

The first patient-practitioner contact is as soon as possible after baseline has been collected by a research assistant. At the first meeting the patient is encouraged to discuss recent events and explore the reasons which they feel led to their current situation. This meeting typically lasts about an hour. The practitioner works with the patient to identify the main social issues they feel precipitated this and discuss relevant agencies that may be able to offer support and information. A plan of action is then worked out with the patient where the patient is given suggestions for services that they can link in with. Treatment as usual for patients with low or no mental health history and risk who present to the hospital Emergency Department is usually referral back to GP; although some might be signposted to services in the community usually by way of leaflets provided. Treatment as usual for patients referred by their GP to Local Primary Mental Health Support Services, is an assessment within 4-8 weeks and appropriate referral or signposting. This intervention goes beyond signposting to assertively link the patient with relevant services to embed them within a supportive network at a time of emergency and vulnerability to try and ameliorate the negative impact of the self harm episode. This 'assertive community linkage' is the basis for the intervention. It differs from signposting by actively encouraging patients to contact relevant community agencies who can provide specialised support and establish a supportive resource to help manage future periods of stress, and following up whether they have made contact with any agencies. Where necessary, the practitioner can make referral or initiate contact and support for patients, for example one patient was keen to attend a local craft group but felt scared to attend alone, the practitioner made contact with the service and arranged for the patient to meet with the craft group co-ordinator alone prior to attending the group to discuss her fears and be reassured.

Follow up contacts are a mix of face-to-face and telephone contacts depending on agreement and discussion with patient. Patients are seen at a location that is convenient to them, this includes home visits, however as part of the community linkage patients are encouraged to engage outside of the home and so meetings are held in local spaces including GP surgeries, coffee shops and arts centres. This is especially the case for patients who do not feel confident or willing to actively engage with available social networks or for whom there is not a local service that suits their needs. In such instances, the practitioner provides a purely contact and listening service, encouraging the patient to leave the house and meet for a chat. Details of all contacts are logged on the FACE electronic recording system used by Hywel Dda University Health Board as their health care notes recoding system. The number and nature (face to face or telephone) and length of contacts vary depending on patient need and are mutually decided between patient and practitioner. The minimum number is four and the maximum is usually six, with the first and final contact always being face to face. As this is a feasibility study we have been flexible with the final number of sessions to accommodate patients who may be waiting for another service. In this situation SWISH provides support until they are engaged with another provider. This has resulted in up to eight sessions in three cases.

This is an important feature of the intervention where as well as providing a stand-alone service linking individuals to community services; it acts as a bridging service for patients. Patients referred to Local Primary Mental Health Support Services and those who have been referred to other (non-secondary) mental health support services such as psychological therapy services typically face a 4-8

week wait for assessment. The intervention provides a point of regular contact and support during this waiting this period.

Control

The control group receive treatment as usual from the service they presented to. This ranges from no action, discharge to GP, signposting to community services and/or referral to psychological therapy services. These treatments do not conflict with SWISH.

Assessments

All patients complete assessments at baseline (before randomisation), 4 weeks and 12 weeks. Those who fall in to the six month period whilst the study is running are invited to complete a 6 month assessment.

Baseline assessments

The baseline assessment consists of the BDI-II, MANSA and CSRI. Patients are asked to complete these questionnaires as soon as possible after they consent. The questionnaires are designed to be self-completed, however the researchers read out the questions and fill in the responses where requested by patients. Researchers note whether they were required to read out any/all questions, and any questions patients have asked for clarity or elaborated upon while completing the questionnaire pack. Patients are given a £10 voucher for the time after completing the baseline assessment.

Follow up assessments

Follow up assessments are conducted with the same questionnaires (BDI-II, MANSA, CSRI) at 4 weeks and 12 weeks. Patients are given no incentive at the 4 week assessment, but those who complete the third assessment at 12 weeks are given a £20 voucher for their time. Early recruits are invited to take part in a 6 month assessment where possible, and a further £10 voucher is given for their time.

All contact with patients is recorded on the health board electronic patient contact recording system.

Patient evaluation and qualitative follow up

At the 12 week data collection patients are asked to complete an evaluation form of their experience of SWISH. There is room for additional comments. The researcher asks for the feedback on the contact and this is recorded verbatim for qualitative analysis, and to provide assessment of the service in the patients' own words. Initially this data was only included for intervention patients, however we have begun to collect it for control as well after control patients commented on the support they felt they were receiving from the researcher collecting assessment data.

Blinding

There is no blinding of researchers or participants. The information sheet clearly states the intervention is a 4-6 week contact programme. The researcher advises all patients that the intervention practitioner will be in touch within a few days if they are randomised to the intervention. It has proved impractical and almost impossible to blind the researcher conducting the

assessments as at week four there is often a clash with intervention meetings for the patient. It would be preferable for all assessments to be collected by the researcher, however due to staffing issues in this trial and to minimise the time commitment on the part of the patient and maximise data collection, intervention patients are given the option to complete the 4 week assessment at an intervention meeting with the practitioner rather than the researcher. Some intervention patients prefer just to have one SWISH contact at the 4 week stage rather than find time for separate meetings with practitioner and researcher. The intervention always includes a discussion of how they are feeling and their social connectedness, so the administration of the questionnaire at the time of intervention avoids some repetition on the part of the patient where the questionnaire is being read to them. However, the majority of questionnaires are completed by respondents individually and put in to an envelope after completion, so the practitioner is unaware of their responses. We acknowledge that this might introduce some bias into the methodology; but for a feasibility study and due to the reasons outlined above, we felt that maximum data return should be prioritised.

Trial Management Group

A Trial Management Group whose members include study applicants (academics and health board practitioners), service users, and representatives of community organisations meets once a quarter to monitor progress and discuss any issues arising. The Chief Investigator also attends a monthly Trial Managers meeting at the Swansea Trials Unit to update on progress and discuss the project.

Analysis

Statistical analysis

Our analysis will be based on the primary and secondary outcome measures which are the BDI-II (Beck Depression Inventory – II) score and MANSA (Manchester Short Assessment of Quality Of Life) and CSRI (Client Services Receipt Inventory). The hypothesis of interest is that the change scores on these outcome measures will be significantly different in the intervention group compared to the control group. We shall analyse changes in all outcome measures between baseline and follow-up at 4 weeks, 12 weeks and (where collected) 6 months by adopting repeated measures analysis of variance. We shall use the pertaining values of the outcome measure under analysis and consider participants' demographic characteristics (e.g. age, marital status, sex education level) as covariates. Since both the BDI-II score and MANSA are well validated and used outcome measures respectively for depression and 'Quality of Life', we would not require checking their internal consistency.

We will adopt the intention-to-treat (ITT) population, consisting of all subjects randomly assigned to the intervention and control. To deal with the missing values, we shall summarise the frequency of missing data for each variable, which affects effective sample size and hence statistical power. If there is no reason to suspect that data are not Missing Completely At Random (MCAR), we shall consider the use appropriate imputation methods to ameliorate the problem of missing data; otherwise, the Trial Statistician and Chief Investigator will further discuss patterns in missing data. Outcome descriptions, summaries and comparisons will be expressed in accordance with appropriate CONSORT guidelines[44], including estimates with 95% confidence intervals to summarise two-tailed tests at the 5% significance level

Health Economics

Health service resource use in primary care, secondary care and the community is collected using the CSRI from participants in both arms of the trial at baseline, 4 weeks, 12 weeks and 6 months.

Questions will relate to all health service contacts (hospital appointments, hospital stays, GP contacts, visiting nurse appointments, etc.) and prescription medicines dispensed during the trial period. Patient recall has been shown to be a valid method for collecting health service resource use data over this period (and, as clinical records are often fragmented, and sometimes unavailable, across different parts of the health service) patient-reported data is likely to remain more readily available and less costly to collect for research purposes[45] . A descriptive analysis of CSRI data, along with estimates of the cost of providing the intervention, will provide a comparison of participant resource use between intervention and control groups, and will provide indicators of the main resource use (and associated costs) drivers of those receiving the intervention.

The CSRI data will be summarised and presented descriptively. The resources utilised and associated costs will be summarised. The costs of the intervention will be estimated. These data will be used to compare the costs of the intervention and usual care and to inform the calculation of incremental costs. The sources of costs will be fully referenced to aid transparency of the analysis. Where possible, published unit costs will be used (e.g. PSSRU Costs of Health and Social Care, British National Formulary, NHS reference costs) using the most recent published sources - 2014/15. Costs (mean and SD and/or 95% confidence intervals or non-parametric equivalent (median and IQRs) will be presented.

Dissemination

Findings will be fed back to the Health Board and to the third sector through presentations and contributions in local publications. Outcomes will be published in peer- reviewed journals and at national and international conferences

DISCUSSION

This paper describes the study protocol for a feasibility study for a randomised controlled trial of a social intervention for people who present with self harm or suicidal ideation and do not require secondary mental health services.

Several limitations apply to this study. Firstly, interventions tend to have a high attrition rate. Dropout can introduce a selection bias and pose a threat to validity. However, we are able to report a high rate of successful intervention completion at 77% across the whole sample. If those who were withdrawn from the study (due to meeting exclusion criteria) are excluded, the completion rate for all those eligible to complete the intervention rises to 83%.

Secondly, the services that SWISH is able to provide are limited. Encouraging social linkage is largely dependent on the availability of relevant options for individuals. In a large, predominantly rural county[46], there are limited choices, which are further reduced if there is no access to transport. A social linkage programme will be able to offer more resources in areas where there are more agencies and community services to engage with. The location and accessibility of services may affect the generalisability of findings to urban populations.

Thirdly, whilst the assessments are intended to be self completed, low literacy levels meant that a substantial number were read out by the researcher. This may have affected responses.

Fourthly, as discussed above, the study was conducted unblinded. Attempts were made to blind the researcher collecting assessments, however this was not practical.

However, even with limitations, the findings will offer an insight in to the applicability of a social intervention to sit alongside medical and psychological interventions. SWISH offers a short term crisis response to engage patients whilst they are waiting for referrals to medical and community services. Often there are 4-8 week waiting lists to be seen by other services. SWISH fills this void and at the very least it offers a contact and listening service to individuals at a vulnerable time. By engaging with patients whilst they are waiting for other appointments it can help reduce rates not attending appointments with other health and social care services by encouraging attendance. Through embedding patients in to existing local organisations and services, SWISH helps to provide a source of support for future stressful times.

TRIAL STATUS

In follow up period of data collection.

FUNDING AND REGISTRATION

The trial is funded by Health and Care Research Wales and sponsored by Swansea University. The trial is registered with the International Standard Randomised Controlled Trial Network (ISRCTN 76914248); and the UK Clinical Research Network (16229)

AUTHOR CONTRIBUTIONS

PH conceived the study in conjunction with RJ and AJ; RJ is clinical supervisor and provides expertise and supervision to practitioners. NA is Chief Investigator and drafted the protocol, designed the study and organised and supervised implementation. AJ and PH provide methodological expertise. SI is trial statistician and developed the statistical analysis strategy and PA developed the health economics strategy. All authors contributed to the preparation of this manuscript, providing comments on drafts approving the final version.

COMPETING INTERESTS

None.

References

1. Cavanagh, J.T.O., Carson, A.J., Sharpe, M., & Lawrie, S.M. (2003) Psychological autopsy studies of suicide: a systematic review, *Psychol. Med*., 33, 395–405

2. Clements, C., Turnbull, P., Hawton, K., Geulayov, G., Waters, K., Ness, J., ... & Kapur, N. (2016). Rates of self-harm presenting to general hospitals: a comparison of data from the Multicentre Study of Self-Harm in England and Hospital Episode Statistics. *BMJ open*, *6*(2), e009749.

3. Welsh Govt (2015) New suicide prevention plan to support most vulnerable, http://www.wales.nhs.uk/news/38065

4. Sinclair, J. M., Gray, A., Rivero-Arias, O., Saunders, K. E., & Hawton, K. (2011). Healthcare and social services resource use and costs of self-harm patients. *Social psychiatry and psychiatric epidemiology*, *46*(4), 263-271

5. Owens, D., Horrocks, J. & House, A. (2002) Fatal and non-fatal repetition of self-harm. Systematic review. *British Journal of Psychiatry*, 181, 193 -199

6. Gilbody, S., House, A., Owens, D,. The early repetition of deliberate self harm. *Journal of the Royal College of Physicians of London* 1997; 31:171–172

7. Hawton, K., Bergen, H., Cooper, J., Turnbull, P., Waters, K., Ness, J., & Kapur, N. (2015). Suicide following self-harm: Findings from the Multicentre Study of self-harm in England, 2000–2012. *Journal of affective disorders*, *175*, 1+ 47-151.

8 . Skegg, K. (2005). Self-harm. *The Lancet*, *366*(9495), 1471-1483

9. Kessler, R. C., Borges, G., & Walters, E. E. (1999). Prevalence of and risk factors for lifetime suicide attempts in the National Comorbidity Survey. *Archives of general psychiatry*, *56*(7), 617-626.

10. Chartrand, H., Bhaskaran, J., Sareen, J., Katz, L. Y., & Bolton, J. M. (2015). Correlates of Nonsuicidal Self-Injury and Suicide Attempts Among Tertiary Care, Emergency Department Patients. *Canadian journal of psychiatry. Revue canadienne de psychiatrie*, *60*(6), 276-283.

11. National Collaborating Centre for Mental Health (UK). Self-Harm: Longer-Term Management. Leicester (UK): British Psychological Society; 2012. (NICE Clinical Guidelines, No. 133.) 7, *Psychological and Psychosocial Interventions*. Available from: http://www.ncbi.nlm.nih.gov/books/NBK126779/

12. Ougrin, D., & Latif, S. (2011). Specific psychological treatment versus treatment as usual in adolescents with self-harm. *Crisis*, 32, pp. 74-80

13. Hepp, U., Wittmann, L., Schnyder, U., & Michel, K. (2004). Psychological and psychosocial interventions after attempted suicide. *Crisis*, *25*(3), 108-117

14. Hawton, K., Saunders, K. E., & O'Connor, R. C. (2012). Self-harm and suicide in adolescents. *The Lancet*, *379*(9834), 2373-2382.

15. National Institute for Clinical Excellence. Self-Harm: The Short Term Physical and Psychological Management and Secondary Prevention of Self-Harm in Primary and Secondary Care. 2004. p. *National Institute for Clinical Excellence*, London (2004).

16. Cooper, J., Steeg, S., Bennewith, O., Lowe, M., Gunnell, D., House, A., ... & Kapur, N. (2013). Are hospital services for self-harm getting better? An observational study examining management, service provision and temporal trends in England. *BMJ open*, *3*(11), e003444.

17. Hickey, L., Hawton, K., Fagg, J., & Weitzel, H. (2001). Deliberate self-harm patients who leave the accident and emergency department without a psychiatric assessment: a neglected population at risk of suicide. *Journal of psychosomatic research*, *50*(2), 87-93.

18. Kapur, N., Steeg, S., Webb, R., Haigh, M., Bergen, H., Hawton, K.. & Cooper, J. (2013). Does clinical management improve outcomes following self-harm? Results from the multicentre study of self-harm in England. *PLoS One*, *8*(8), e70434.

19. Bancroft, J., Skrimshire, A., Casson, J., Harvard-Watts, O., & Reynolds, F. (1977). People who deliberately poison or injure themselves: their problems and their contacts with helping agencies. *Psychological medicine*, *7*(02), 289-303.

20. Haw, C., & Hawton, K. (2008). Life problems and deliberate self-harm: associations with gender, age, suicidal intent and psychiatric and personality disorder. *Journal of Affective Disorders*, *109*(1), 139-148.

21. Kposowa, A. J. (2000). Marital status and suicide in the National Longitudinal Mortality Study. *Journal of epidemiology and community health*, *54*(4), 254-261.

22. Barr, B., Taylor-Robinson, D., Scott-Samuel, A., McKee, M., & Stuckler, D. (2012). Suicides associated with the 2008-10 economic recession in England: Time trend analysis.

23. Stack, S. (2000). Suicide: a 15-year review of the sociological literature part II: modernization and social integration perspectives. *Suicide and Life-Threatening Behavior*, *30*(2), 163-176.

24. Webb, L. (2002). Deliberate self-harm in adolescence: a systematic review of psychological and psychosocial factors. *Journal of Advanced Nursing*, 38, 235–244

25. Hawton, K. Arensman, E. Townsend, E. Bremner, S. Feldman, E. Goldney, R. Gunnell, D. Hazell, P. Van Heeringen, K. House, A. Owens, D. Sakinofsky, I. & Traskman-Bendz, L. (1998). Deliberate self-harm: Systematic review of efficacy of psychosocial and pharmacological treatments in preventing repetition. *British Medical Journal, 317,* 441-447.

26. Townsend, E. Hawton, K. Altman, D.G. Arensman, E. Gunnell, D. Hazell, P. House, A. & Van Heeringen, K. (2001). The efficacy of problem-solving treatments after deliberate self-harm: Meta-analysis of randomised controlled trials with respect to depression, hopelessness and improvement in problems. *Psychological Medicine, 31,* 979-988.

27. De Leo, D., Buono, M. D., & Dwyer, J. (2002). Suicide among the elderly: the long-term impact of a telephone support and assessment intervention in northern Italy. *The British journal of psychiatry*, *181*(3), 226-229.

28. Milner, A. J., Carter, G., Pirkis, J., Robinson, J., & Spittal, M. J. (2015). Letters, green cards, telephone calls and postcards: systematic and meta-analytic review of brief contact interventions for reducing self-harm, suicide attempts and suicide. *The British Journal of Psychiatry*, *206*(3), 184-190.

29. Kapur, N., Cooper, J., Bennewith, O., Gunnell, D., & Hawton, K. (2010). Postcards, green cards and telephone calls: therapeutic contact with individuals following self-harm. *The British Journal of Psychiatry*, *197*(1), 5-7

30. Chioqueta, A. P., & Stiles, T. C. (2007). The relationship between psychological buffers, hopelessness, and suicidal ideation: identification of protective factors. *Crisis*, *28*(2), 67-73.

31. Kapur, N. Cooper, J. Bennewith, O. Gunnell, D. & Hawton, K. (2010). Postcards, green cards and telephone calls: Therapeutic contact with individuals following self-harm. *The British Journal of Psychiatry, 197,* 5-7

32. Milner, A.J. Carter. G. Pirkis, J. Robinson, J. & Spittal, M.J. (2015). Letters, green cards, telephone calls and postcards: Systematic and meta-analytic review of brief contact interventions for reducing self-harm, suicide attempts and suicide. *British Journal of Psychiatry, 206(3),* 184-190.

33. Petrakis, M., & Joubert, L. (2013). A social work contribution to suicide prevention through assertive brief psychotherapy and community linkage: Use of the Manchester Short Assessment of Quality of Life (MANSA).*Social work in health care*, *52*(2-3), 239-257

34. Beck, A. T., Steer, R. A., & Brown, G. K. (1996). Beck depression inventory-II. *San Antonio, TX: Psychological Corporation*, b9.

35. Simon, G. E., Rutter, C. M., Peterson, D., Oliver, M., Whiteside, U., Operskalski, B., & Ludman, E. J. (2013). Does response on the PHQ-9 depression questionnaire predict subsequent suicide attempt or suicide death?. *Psychiatric services*.64, 12, 1195-1202

36. Priebe, S., Huxley, P., Knight, S., & Evans, S. (1999). Application and results of the Manchester Short Assessment of Quality of Life (MANSA).*International journal of social psychiatry*, *45*(1), 7-12

37. Beecham, J., & Knapp, M. (2001) Costing psychiatric interventions. In: Thornicroft G, ed. Measuring Mental Health Needs, 2nd edn. London: Gaskell, pp200–224

38. Lyons RA, Jones KH, John G, Brooks CJ, Verplancke JP, Ford DV, Brown G, & Leake K. (2009). The SAIL databank: linking multiple health and social care datasets. BMC Medical Informatics and Decision Making, 9(1), 3-25

39.Ford DV, Jones KH, Verplancke JP, Lyons RA, John G, Brown G, Brooks CJ, Thompson S, Bodger O, Couch T & Leake K. (2009). The SAIL Databank: building a national architecture for e-health research and evaluation. BMC Health Services Research, 9(1), 157

40. Baguley, T. (2012). *Serious stats: A guide to advanced statistics for the behavioral sciences*. Palgrave Macmillan.

41. Frasure-Smith, N., Lespérance, F., Prince, R. H., Verrier, P., Garber, R. A., Juneau, M., ... & Bourassa, M. G. (1997). Randomised trial of home-based psychosocial nursing intervention for patients recovering from myocardial infarction. *The Lancet*, *350*(9076), 473-479.

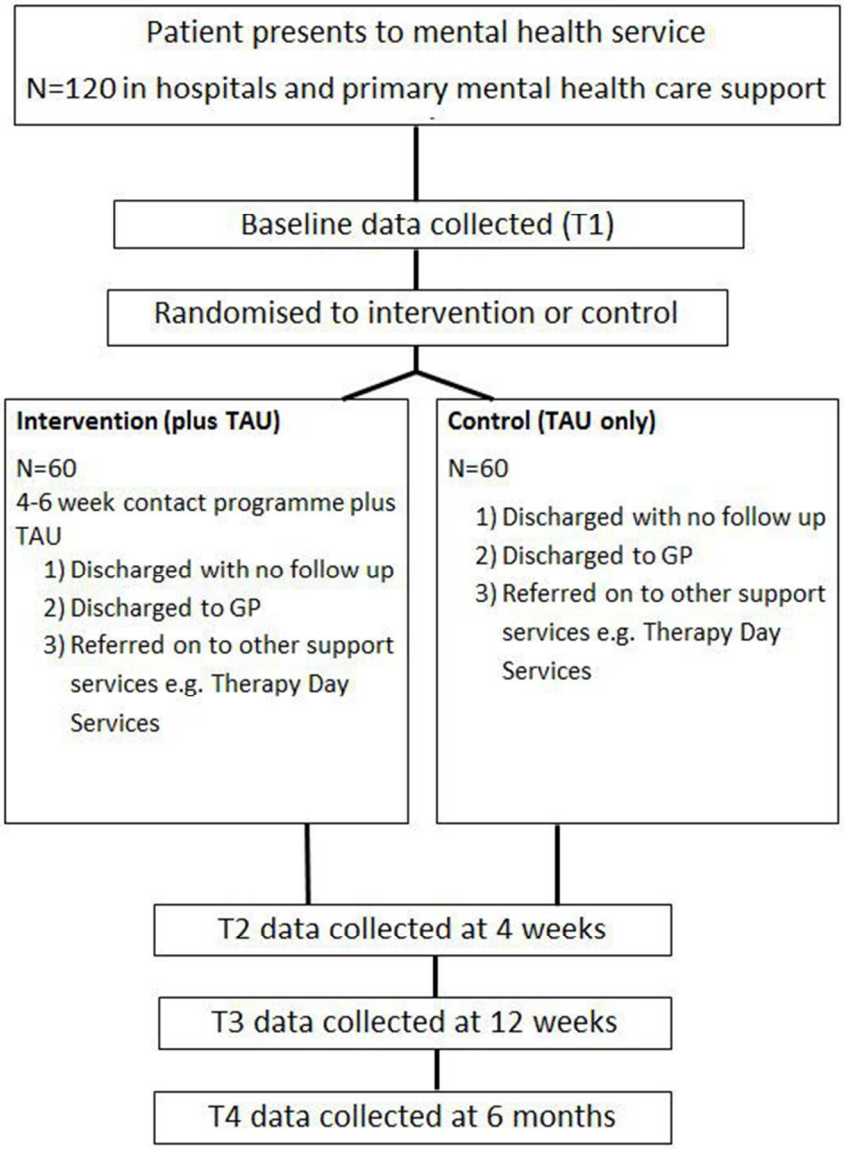
42. Merrill, R. M. (2016). *Statistical Methods in Epidemiologic Research*. Jones & Bartlett Publishers.

43. Lindley, D. V., & Scott, W. F. (1984). New Cambridge Statistical Tables Cambridge.

44. Schulz, K. F., Altman, D. G., & Moher, D. (2010). CONSORT 2010 statement: updated guidelines for reporting parallel group randomised trials. *BMC medicine*, *8*(1), 1.

45. Ridyard, C. & Hughes, D. (2013) Review and the use of resource instruments based on patient recall in relation to other methods pf resource use estimation. *Trials*, 14, 1-1

46. Periman, B. Hartman, E. A. & Bosak, J. (1984) A study of mental health administrators and systems utilising a four-part urban/rural taxonomy. *Community Mental Health Journal.* 20(3), 202-211



Study chart
see Figure 1

SPIRIT
STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number of manuscript
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	1, 11
	2b	All items from the World Health Organization Trial Registration Data Set	N/A
Protocol version	3	Date and version identifier	N/A
Funding	4	Sources and types of financial, material, and other support	10
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1
	5b	Name and contact information for the trial sponsor	11
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	N/A
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	9
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each	2-3

		intervention	
	6b	Explanation for choice of comparators	3
Objectives	7	Specific objectives or hypotheses	3
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	3
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	3
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	4
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	4
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	5
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	N/A
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	6
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	3,9
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	8
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	4
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	N/A
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is	4

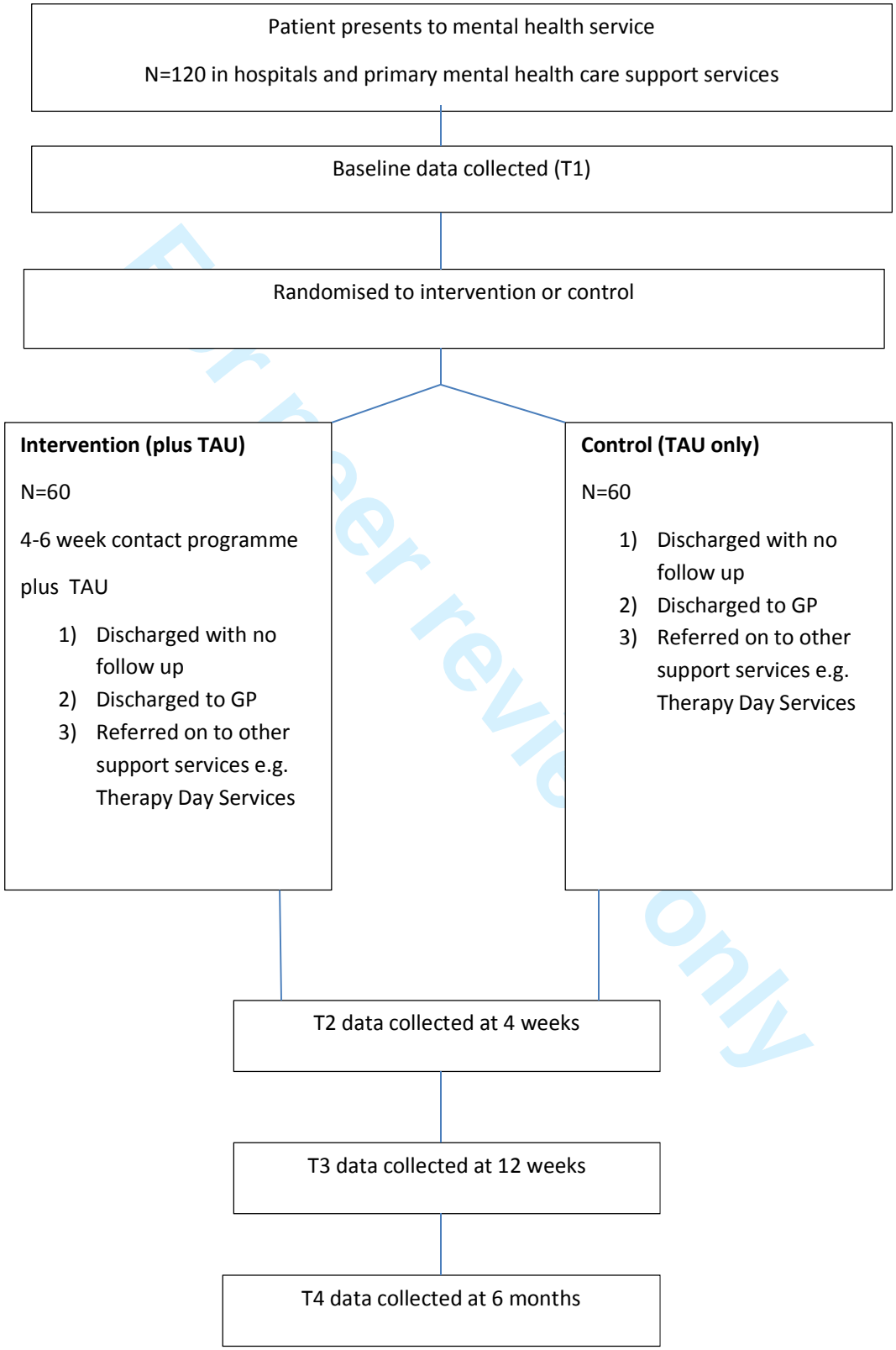
		unavailable to those who enrol participants or assign interventions	
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	4
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	4
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	7
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	N/A
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	6
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	4
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	9
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	9 Contact statistician for more information
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	Contact statistician
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	Contact statistician
Methods: Monitoring			

Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	This is a feasibility study so no formal DMC in place,. However Swansea Trials Unit are managing the data and data is collected in accordance with their regulations
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	N/A
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	N/A
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	None in place formally as this is a feasibility study, but the sponsor has its internal audit process that the trial is subject to.
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	1
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	N/A
Consent or	26a	Who will obtain informed consent or assent from potential trial participants or authorised	3

assent		surrogates, and how (see Item 32)	
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	10
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	N/A
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	N/A
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N/A
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	N/A
	31b	Authorship eligibility guidelines and any intended use of professional writers	N/A
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	N/A
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	attached separately/available from CI
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

Recruitment chart CONSORT statement (NB this chart is included in main document)



BMJ Open

Investigating the feasibility of an enhanced contact intervention in self harm and suicidal behaviour: A protocol for a randomised controlled trial delivering a Social support and Wellbeing Intervention following Self Harm (SWISH)

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2016-012043.R2
Article Type:	Protocol
Date Submitted by the Author:	19-Jul-2016
Complete List of Authors:	Ahmed, Nilufar; Swansea University College of Human and Health Sciences, Public Health, Policy and Social Sciences John, Ann; Swansea University, Farr Institute Islam, Saiful; Swansea University, College of Medicine Jones, Richard; Hywel Dda Health Board Anderson, Pippa; Swansea University, Centre for Health Economics Davies, Charlotte; Hywel Dda Health Board Khanom, Ashrafunnesa; Swansea University, School of Medicine Harris, Shaun; Swansea University, Farr Institute Huxley, Peter; Bangor University
Primary Subject Heading:	Mental health
Secondary Subject Heading:	Health services research, Mental health
Keywords:	randomised controlled trial, self harm, intervention, depression, social support, suicide prevention

Investigating the feasibility of an enhanced contact intervention in self harm and suicidal behaviour: A protocol for a randomised controlled trial delivering a Social support and Wellbeing Intervention following Self Harm (SWISH)

Nilufar Ahmed*[1], Ann John[1], Saiful Islam[1,], Richard Jones[2] , Pippa Anderson[1], Charlotte Davies[2], Ashra Khanom[1], Shaun Harris, Peter Huxley[3]

Abstract

Introduction: Self harm is a strong predictor for suicide. Risks for repeat behaviour are heightened in the aftermath of an index episode. There is no consensus on the most effective type of intervention to reduce repetition. Treatment options for patients who do not require secondary mental health services include: no support, discharge to General Practitioner, or referral to primary care mental health support services. The aim of this study is to assess whether it is feasible to deliver a brief intervention after an episode and whether this can reduce depressive symptoms and increase sense of wellbeing for patients who self harm.

Methods: This is a non-blinded parallel group randomised clinical trial. One hundred and twenty patients presenting with self harm and/or suicidal ideation to mental health services over a twelve month period who are not referred to secondary services will be randomised to either intervention plus treatment as usual (TAU), or control (TAU only). Patients are assessed at baseline, 4 weeks and 12 weeks with standardised measures to collect data on depression, wellbeing, and service use. Primary outcome is depression scores; secondary outcomes are wellbeing scores and use of services. The findings will indicate whether a rapid response brief intervention is feasible and can reduce depression and increase wellbeing among patients who self harm and do not require secondary services.

Ethics and dissemination: Ethical approval was granted by the UK National Health Service (NHS) Ethics Committee process (REC 6: 14/WA/0074). The findings of the trial will be disseminated through presentations to the participating Health Board and partners, peer-reviewed journals, national and international conferences.

Trial registration: The trial is registered with the International Standard Randomised Controlled Trial Network (ISRCTN 76914248); and UK Clinical Research Network (16229)

Keywords: Randomised controlled trial, Self Harm, Suicide, Intervention, Social wellbeing, Social support, Social networks, Depression

*Corresponding Author:
Dr Nilufar Ahmed
27 Haldane Building
College of Human and Health Sciences
Swansea University, Singleton Park, Swansea, SA2 8PP
01792 602819
n.ahmed@swansea.ac.uk
[1]Swansea University
[2]Hywel Dda University Health Board
[3]Bangor University

Strengths and limitations of the study

- Development of an intervention for people who have little or no support following self harm.
- Focus on social issues that are present in the person's life
- A cost-effective intervention that can work alongside existing services, supporting patients during a vulnerable time and keeping them engaged whilst they are awaiting assessment from other services.
- Strong retention rate for trial
- Data linkage for long term follow up
- Social linkage relies on access to services and transport that can inhibit those without means and access
- Unblinded trial
- No social outcome measures collected

Background

Self-harm is the strongest risk factor for future suicide[1] resulting in over 200,000 hospital presentations annually in England and Wales[2, 3] and is associated with high personal, social and medical costs[4]. Repetition is common, with between 15-25% re-presenting to the same hospital within a year of the index episode.[5] The highest risk of repeat self harm is within 3-6 months after the index episode[6] with the risk for suicide in the year following self harm almost 50 times higher than in the general population.[7]

Depressive symptoms are prevalent amongst those with self harm and suicidal ideation[8] and suicidal ideation is strongly linked with progression to suicide attempt.[9] Due to the strong link between a mental health condition and self harm,[10] the majority of interventions are based on psychological and medical approaches.[11] Whilst depression is an established and consistent predictor for self harm, not all of those who present with self harm have, or are diagnosed with, a mental health condition.[12,13] NICE guidelines explicitly state that patients who present with self harm should receive a psychosocial assessment.[14] However this is often not routinely offered[15] and many patients who present to the emergency department with self harm are discharged without any assessment[16] despite evidence that psychosocial assessment is associated with lower risk of repetition.[17] Presentations to hospital tend to prioritise risk factors to determine medical needs, admission, referral, or discharge, above psychosocial needs. A lack of psychosocial assessment leaves much of the impact of social situations under examined. Whilst addressing immediate psychological and medical needs are vital, a lack of exploration of the social milieu of the patient may miss important factors that might have been precipitous in the self harm behaviour and therefore may be a recurring antecedent for self harm. It is known that most patients who present with self harm have numerous social and interpersonal problems which catalyse self harm behaviour.[18] In the absence of routine psychosocial assessments,[15] patients who present with self harm and who do not have a known history of mental health problems, often receive little or no support from health care services, with signposting to community services or discharge to General Practitioner (GP) being the main course of management. Supporting such individuals who do not require secondary mental health services to deal with stressors and enabling them to better manage stressors may help alleviate their impact and thus reduce rates of self harm as a response to ongoing or repeated stress.

There have been calls to explore social factors when assessing self harm as they are increasingly being identified as instrumental in self harm.[19] Studies report that as many as 70% of self harm episodes are triggered by interpersonal problems.[20] The importance of recognising and responding to social factors in self harm and suicide prevention has been described in the literature.[21] There is global evidence of significant increases in suicide rates following economic recession[22] with unemployment being strongly linked with suicide for men and women.[21] Research has also linked an elevated risk of suicide with isolation and a lack of social integration.[23]

There is little effective primary care prevention for patients who self harm either as a first episode or repeatedly.[24] Numerous interventions have been trialled in attempting to reduce self harm and suicidal behaviour.[25,26] These vary significantly in content, and no single type of intervention has been found to deliver consistent results. Positive outcomes in reducing self harm have been reported for non-pharmacological interventions[27] such as provision of an emergency access card.[28] Findings from contact interventions vary, with some reporting long term positive impacts.[29,30,31,32] Contact interventions, including telephone, postcard and letter interventions offer a cost-effective way of supporting individuals by reducing a sense of isolation and increasing a sense of social connectedness; it has been argued that perceived connectedness can reduce suicidal ideation.[32] An elevated sense of support may encourage help seeking at times of crisis.[32] Reviews of contact-based interventions (e.g. postcards, crisis cards, telephone calls) after admission to hospital have found inconsistent results across studies and concluded that more research is needed.[31,32]

This study draws on findings that suggest increasing social support through contact based interventions can support those who self harm and reduce suicide rates.[30] An Australian study[33] reported an intervention focussing on connecting individuals to relevant and available support led to a reduction in depression scores and an increase in wellbeing. This study adapts that intervention to offer a brief non-psychological and non-medical intervention delivered by trained practitioners. Initially we intended to replicate the study, but a difference in health care systems and access across Australia and the UK, means that a full replication is not possible. In remaining as close to that study we are using the same outcome measures they applied – BDI-II (Beck Depression Inventory – II)[34] to measure depression and MANSA (Manchester Short Assessment of Quality Of Life)[35] to measure quality of life. Additionally we are collecting the CSRI (Client Services Receipt Inventory)[36] to measure service use and the study is registered with the Secure Anonymised Information linkage (SAIL) database for a one year follow up of service use.[37,38]

The aim of this study is to assess whether an enhanced contact intervention is beneficial for patients who present with self harm and/or suicidal ideation but are not referred to secondary services. We define it as an enhanced contact intervention as it goes further than what is usually termed contact intervention in the literature. Contact interventions tend to be more remote and use postcards or phonecalls.[29,30,31] Our intervention involves regular face to face contact. It focuses on social factors and actively links individuals to services that can help with social problems including financial issues, housing, relationship difficulties, employment, literacy etc. The intervention is flexible to meet the needs of the patient; it does not require patients to engage with services if they are not ready; for such patients, regular contact with the intervention practitioner provides support and a source of social contact at a vulnerable time. The intervention goes beyond signposting with assertively linking the individual to relevant support agencies (e.g. community organisations) that already exist. By doing so, the individual becomes embedded in to a support network which they can draw on at future times of stress.

METHOD

Design and setting

This is a randomised controlled trial (RCT) conducted by Swansea University in partnership with Hywel Dda University Health Board (HDUHB) running between January 2015-March 2016 in Carmarthenshire, West Wales. The trial delivers a brief contact intervention to patients over 18 who present to Mental Health Services (defined as hospital Emergency Department and Local Primary Mental Health Support Services) who would ordinarily be referred back to primary care and/or community services. Patients who require admission or crisis intervention are excluded from SWISH and referred to appropriate services. Patients who meet the inclusion criteria are randomised to the intervention or control group. The intervention is a 4-6 week programme of face to face and phone call contact tailored to meet the needs of the individual in addition to Treatment As Usual (TAU) which ranges from discharge with no further support, signposting via leaflets to community organisations, or referral to primary care for ongoing care. The control arm is just Treatment As Usual. The full duration of patient participation is 12 weeks with assessments collecting standardised measures for depression, wellbeing, and service use conducted for all patients at baseline, 4 weeks and 12 weeks. Where possible a 6 month follow up using the same measures will be sought (see Figure 1).

Study population

Patients who present to Mental Health Services (either directly to hospital, or indirectly through referral from General Practitioner to Local Primary Mental Health Support Services) with self harm and/or suicidal ideation are assessed by Mental Health Practitioners at these sites and those thought suitable for SWISH are referred to SWISH in addition to their treatment as usual. A SWISH worker conducts a further eligibility test based on inclusion and exclusion criteria before inviting a patient who meets the requirements to participate. Patients are given a study information leaflet and time to consider whether they would like to take part. Written consent is obtained by the research assistant prior to baseline data collection. Once baseline data has been collected patients are randomly assigned to either intervention or control.

Inclusion criteria:

Person aged 18 or over who presents to Mental Health Services with self harm and/or suicidal ideation and is assessed by a Mental Health Practitioner at these sites to not require secondary mental health services and be suitable for SWISH.

Exclusion criteria:

Anyone who following assessment by a Mental Health Practitioner, meets at least one of the following criteria:

- unable to give informed consent
- requires admission to a mental health inpatient unit
- requires secondary mental health services
- assessed as high risk for violence
- known or assessed to have a severe mental illness and require other services
- is under a current and active care and treatment plan with Adult Mental Health Services
- is unable to communicate in English

At any point, if a recruited patient meets any of the exclusion criteria they are withdrawn from the study, but their anonymised data will be retained for analysis.

Power and sample size

The power analysis is based on the primary outcome measure, BDI-II score. Based on published reviews and papers, a five to ten percent change in the BDI-II score represents a clinically important difference and the standard deviation varies between 6 to 10 [39,40,41] which provides an effect size of approximately 0.53. To detect a five to ten point difference in the BDI mean score between intervention and the control conditions, with 80% power, requires a sample size of 120 (60 in each arm of the trial).

As this study is assessing feasibility for a full trial of a new intervention, we cannot anticipate the attrition rate, but will use the attrition at 6 and 12 weeks to inform the full trial. For the same reason there are no stopping guidelines, except the complete failure to recruit to the required sample size.

Randomisation

We performed an individual randomisation of the patients from the study population who met the inclusion criteria. As this is a feasibility study we did not use any stratification for randomisation (e.g. stratify between ideators and self harmers). We will be looking at differences during analysis, and should there be any significant differences we intend to incorporate stratification in the future full trial. Patients are randomised after completion of baseline assessment by the Intervention Practitioner using an online randomisation tool managed by Swansea Trials Unit. Patients are randomised with a ratio of 1:1 to intervention and control and used random numbers generated from the *New Cambridge Statistical Table.*[42]

Intervention

The intervention is a 4-6 week enhanced contact programme which is a mix of face to face and telephone contact. It deliberately steers away from being a psychological or medical service; rather it is based on linking individuals into social support networks and encouraging access to, and engagement with, relevant services. It is an additional rather than alternative service for support services already in place, and encourages patients to engage with existing services. As such, as long as patients are not receiving support from secondary mental health services (an exclusion criteria based on higher support needs of secondary mental health service users); there is no contraindication to involvement with SWISH.

An awareness of local third sector services is key to the role of the practitioner. The intervention can be delivered by a skilled individual who has experience of working with people with mental health issues. The practitioners delivering the intervention in this trial have worked in mental health services but are not registered mental health practitioners. They have experience of working in Carmarthenshire within mental health services and/or developing mental health services for vulnerable populations. By not requiring practitioners to hold registrations, the intervention is more cost effective to deliver as it relies on locality-based training and awareness above registration. A condition of employment is to have enhanced Disclosure and Barring Service clearance before commencement. The practitioners receive training on mental health service delivery in Carmarthenshire from an Advanced Nurse Practitioner in mental health services. Formal clinical supervision with the Advanced Nurse Practitioner is once a fortnight or more depending on requirements; the supervisor is available at all times on the phone for immediate questions, and monitors the delivery of the intervention and patient contact.

The intervention encourages individuals to link with local services. In this trial some of the agencies patients are linked into include Men's Shed projects, adult education courses, knitting groups and volunteering services; as well as services supporting individuals with drug and alcohol issues and domestic abuse. The choice of service is decided alongside the patient based on the type of support and engagement they would like. The intervention primarily focuses on the social dimensions of a person's life; the medical and psychological needs of the patient will have been assessed prior to the patient's referral to SWISH. If at any time during the intervention the practitioner is concerned that these needs may be escalating and require specialised support, or there is a crisis situation this will be immediately discussed with the clinical supervisor who will refer the patient accordingly; and SWISH will continue to support the patient for the duration of the intervention, or until they meet the exclusion criteria and are engaged with relevant support services.

The first patient-practitioner contact is as soon as possible after baseline has been collected by a research assistant. At the first meeting the patient is encouraged to discuss recent events and explore the reasons which they feel led to their current situation. This meeting typically lasts about an hour. The practitioner works with the patient to identify the main social issues they feel precipitated this and they discuss relevant agencies that may be able to offer support and information. A plan of action is then worked out with the patient where the patient is given suggestions for services that they can link in with.

Treatment as usual for patients with low or no mental health history who present to the hospital Emergency Department is usually referral back to GP; although some might be signposted to services in the community usually by way of leaflets provided. Treatment as usual for patients referred by their GP to Local Primary Mental Health Support Services, is an assessment within 4-8 weeks and appropriate referral or signposting. This intervention goes beyond signposting to assertively link the patient with relevant services to embed them within a supportive network at a time of emergency and vulnerability to try and ameliorate the negative impact of the self harm episode. This 'assertive community linkage' is the basis for the intervention. It differs from signposting by actively encouraging patients to contact relevant community agencies who can provide specialised support and establish a supportive resource to help manage future periods of stress. The practitioner can follow up whether they have made contact with any agencies and explore reasons for reluctance to engage. Where necessary, the practitioner can make referral or initiate contact and support for patients, for example one patient was keen to attend a local craft group but felt scared to attend alone, the practitioner made contact with the service and arranged for the patient to meet with the craft group co-ordinator alone prior to attending the group to discuss her fears and be reassured.

Follow up contacts are a mix of face to face and telephone contacts depending on agreement and discussion with patient. Patients are seen at a location that is convenient to them, this includes home visits, however as part of the community linkage patients are encouraged to engage outside of the home and so meetings are held in local spaces including GP surgeries, coffee shops and arts centres. This is especially the case for patients who do not feel confident or willing to actively engage with available social networks or for whom there is not a local service that suits their needs. In such instances, the practitioner provides a purely contact and listening service, encouraging the patient to leave the house and meet for a chat. Details of all contacts are logged on the FACE electronic recording system used by Hywel Dda University Health Board as their health care notes recording system. The number and nature (face to face or telephone) and length of contacts vary depending on patient need and are mutually decided between patient and practitioner. The minimum number is four and the maximum is usually six, with the first and final contact always being face to face. As this is a feasibility study we have been flexible with the final number of sessions to accommodate

patients who may be waiting for another service. In this situation SWISH provides support until they are engaged with another provider. This has resulted in up to eight sessions in three cases.

This is an important feature of the intervention where as well as providing a stand-alone service linking individuals to community services it acts as a bridging service for patients. Patients referred to Local Primary Mental Health Support Services and those who have been referred to other (non-secondary) mental health support services such as psychological therapy services typically face a 4-8 week wait for assessment. The intervention provides a point of regular contact and support during this waiting period.

Control

The control group receive treatment as usual from the service they presented to. This ranges from no action, discharge to GP, signposting to community services and/or referral to psychological therapy services. These treatments do not conflict with SWISH.

Outcome measures

The primary outcome measure is the BDI-II, measuring depressive symptoms as this was the primary outcome measure in the Australian study. For the same reason our secondary outcome assesses whether a social intervention leads to overall increase in wellbeing, as measured by the MANSA. Additionally we are collecting data on whether the intervention reduces rates of representation to mental health services as measured by the CSRI and long term follow up of service use by SAIL.

Our choice of primary and secondary outcomes is based on remaining as close to the Australian study as possible based on the information available. For a further trial we will seek to collect data on social outcomes, exploring the type and nature of social networks that individuals engage with as an outcome of the intervention.

Assessments

All patients complete assessments at baseline (before randomisation), 4 weeks and 12 weeks. Those who fall in to the six month period whilst the study is running are invited to complete a 6 month assessment. A one year follow up will be conducted by SAIL.

Baseline assessments

The baseline assessment consists of the BDI-II, MANSA and CSRI. Patients are asked to complete these questionnaires as soon as possible after they consent. The questionnaires are designed to be self-completed, however the researchers read out the questions and fill in the responses where requested by patients. Researchers note whether they were required to read out any/all questions, and any questions patients have asked for clarity or elaborated upon while completing the questionnaire pack. Patients are given a £10 voucher for their time after completing the baseline assessment. All contact with patients is recorded on the health board electronic patient contact recording system.

Follow up assessments

4 week follow up

Follow up assessments are conducted with the same questionnaires (BDI-II, MANSA, CSRI) at 4 weeks. Patients are given no incentive at the 4 week assessment.

12 week follow up

Patients are asked to complete the BDI-II, MANSA and CSRI. Patients who complete the 12 week assessment are given a £20 voucher for their time.

Additionally at the 12 week data collection patients are asked to complete an evaluation form of their experience of SWISH. There is room for additional comments. The researcher asks for the feedback on the contact and this is recorded verbatim for qualitative analysis, and to provide assessment of the service in the patient's own words. Initially this data was only included for intervention patients, however we have begun to collect it for control as well after control patients commented on the support they felt they were receiving from the researcher collecting assessment data.

Six month follow up

Early recruits are invited to take part in a 6 month assessment where possible, and a further £10 voucher is given for their time.

One year follow up

Patients have consented to being linked in anonymously to the SAIL Databank (http://www.saildatabank.com/). SAIL contain routinely collected anonymous data for Wales. We will use the SAIL data for the number of visits (or contacts) to primary (General Practitioner) and secondary care (Hospital admission and Emergency Department visit) by the SWISH patients for the year preceding and the year following the intervention. We will be collecting the counts of contacts that relate to self-harm, suicidal ideation and depression.

Blinding

There is no blinding of researchers or participants. The information sheet clearly states the intervention is a 4-6 week contact programme. The researcher advises all patients that the intervention practitioner will be in touch within a few days if they are randomised to the intervention. It has proved impractical and almost impossible to blind the researcher conducting the assessments as at the week four assessment there is often a clash with intervention meetings for the patient. It would be preferable for all assessments to be collected by the researcher, however due to staffing issues in this trial and to minimise the time commitment on the part of the patient and maximise data collection, intervention patients are given the option to complete the 4 week assessment at an intervention meeting with the practitioner rather than the researcher. Some intervention patients prefer just to have one SWISH contact at the 4 week stage rather than find time for separate meetings with practitioner and researcher. The intervention always includes a discussion of how they are feeling and their social connectedness, so the administration of the questionnaire at the time of intervention avoids some repetition on the part of the patient where the questionnaire is being read to them. However, the majority of questionnaires are completed by respondents individually and put in to an envelope after completion, so the practitioner is unaware of their responses. We acknowledge that this might introduce some bias into the methodology; but for a feasibility study and due to the reasons outlined above, we feel that maximum data return should be prioritised.

Trial Management Group

A Trial Management Group whose members include study applicants (academics and health board practitioners), service users, and representatives of community organisations meets once a quarter to monitor progress and discuss any issues arising. The Chief Investigator also attends a monthly Trial Managers meeting at the Swansea Trials Unit to update on progress and discuss the project.

Analysis

Statistical analysis

Our analysis will be based on the primary and secondary outcome measures which are the BDI-II score and MANSA and CSRI. The hypothesis of interest is that the change scores on these outcome measures will be significantly different in the intervention group compared to the control group. We will analyse changes in all outcome measures between baseline and follow-up at 4 weeks, 12 weeks and (where collected) 6 months by adopting repeated measures analysis of variance. We shall use the pertaining values of the outcome measure under analysis and consider participants' demographic characteristics (e.g. age, marital status, sex education level) as covariates. Since both the BDI-II score and MANSA are well validated and use outcome measures respectively for depression and 'Quality of Life', they do not require checking of internal consistency.

As described above, we will be using SAIL to compare the number of contacts to the primary and secondary care made by the SWISH patients before and after the intervention between the case and control group. We will use a t-test check whether there is any statistical significance difference between the groups.

We will adopt the intention-to-treat (ITT) population, consisting of all subjects randomly assigned to the intervention and control. To deal with the missing values, we shall summarise the frequency of missing data for each variable, which affects effective sample size and hence statistical power. If there is no reason to suspect that data are not Missing Completely At Random (MCAR), we shall consider the use appropriate imputation methods to ameliorate the problem of missing data; otherwise, the Trial Statistician and Chief Investigator will further discuss patterns in missing data. Outcome descriptions, summaries and comparisons will be expressed in accordance with appropriate CONSORT guidelines,[43] including estimates with 95% confidence intervals to summarise two-tailed tests at the 5% significance level.

Health Economics

Health service resource use in primary care, secondary care and the community is collected using the CSRI from participants in both arms of the trial at baseline, 4 weeks, 12 weeks and 6 months. Questions will relate to all health service contacts (hospital appointments, hospital stays, GP contacts, visiting nurse appointments, etc.) and prescription medicines dispensed during the trial period. Patient recall has been shown to be a valid method for collecting health service resource use data over this period (and, as clinical records are often fragmented, and sometimes unavailable, across different parts of the health service) patient-reported data is likely to remain more readily available and less costly to collect for research purposes.[44] A descriptive analysis of CSRI data, along with estimates of the cost of providing the intervention, will provide a comparison of participant resource use between intervention and control groups, and will provide indicators of the main resource use (and associated costs) drivers of those receiving the intervention.

The CSRI data will be summarised and presented descriptively. The resources utilised and associated costs will be summarised. The costs of the intervention will be estimated. These data will be used to compare the costs of the intervention and usual care and to inform the calculation of incremental costs. The sources of costs will be fully referenced to aid transparency of the analysis. Where possible, published unit costs will be used (e.g. PSSRU Costs of Health and Social Care, British National Formulary, NHS reference costs) using the most recent published sources - 2014/15. Costs (mean and SD and/or 95% confidence intervals or non-parametric equivalent (median and IQRs) will be presented.

Dissemination

Findings will be fed back to the Health Board and to the third sector through presentations and contributions in local publications. Outcomes will be published in peer- reviewed journals and at national and international conferences

DISCUSSION

This paper describes the study protocol for a feasibility study for a randomised controlled trial of a an enhanced contact intervention for people who present with self harm or suicidal ideation and do not require secondary mental health services.

Several limitations apply to this study. Firstly, interventions tend to have a high attrition rate. Dropout can introduce a selection bias and pose a threat to validity. However, we are able to report a high rate of recruitment at a 100% of our target and successful intervention completion at 77% across the whole sample. If those who were withdrawn from the study (due to meeting exclusion criteria) are excluded, the completion rate for all those eligible to complete the intervention rises to 83%.

Secondly, the services that SWISH is able to provide are limited. Encouraging social linkage is largely dependent on the availability of relevant options for individuals. In a large, predominantly rural county,[45] there are limited choices, which are further reduced if there is no access to transport. A social linkage programme will be able to offer more resources in areas where there are more agencies and community services to engage with. The location and accessibility of services may affect the generalisability of findings to urban populations.

Thirdly, whilst the assessments are intended to be self-completed, a lack of confidence on the part of patients in completing questionnaires themselves, meant that a substantial number were read out by the researcher. This may have affected responses.

Finally, as discussed above, the study was conducted unblinded. Attempts were made to blind the researcher collecting assessments, however this was not practical.

However, even with limitations, the findings will offer an insight in to the applicability of a social intervention to sit alongside medical and psychological interventions. SWISH offers a short term crisis response to engage patients whilst they are waiting for referrals to medical and community services. Often there are 4-8 week waiting lists to be seen by other services. SWISH fills this void and at the very least it offers a contact and listening service to individuals at a vulnerable time. By

engaging with patients whilst they are waiting for other appointments it can help reduce rates not attending appointments with other health and social care services by encouraging attendance. Through embedding patients in to existing local organisations and services, SWISH helps to provide a source of support for future stressful times.

TRIAL STATUS

In follow up period of data collection.

FUNDING AND REGISTRATION

The trial is funded by Health and Care Research Wales and sponsored by Swansea University. The trial is registered with the International Standard Randomised Controlled Trial Network (ISRCTN 76914248); and the UK Clinical Research Network (16229)

AUTHOR CONTRIBUTIONS

NA is Chief Investigator and drafted the protocol, designed the study and organised and supervised implementation. PH conceived the study in conjunction with RJ and AJ; AJ and PH provide methodological expertise. SI is trial statistician and developed the statistical analysis strategy. RJ is clinical supervisor and provides expertise and supervision to practitioners. PA and SH developed the health economics strategy. AK and CD worked on the data collection and data management. NA, AJ and SI worked on the preparation of this manuscript, and all authors provided comments on drafts and approved the final version.

COMPETING INTERESTS

None.

References

1. Cavanagh JT, Carson AJ, Sharpe M, Lawrie SM. Psychological autopsy studies of suicide: a systematic review. Psychological medicine. 2003 Apr 1;33(03):395-405.

2. Clements C, Turnbull P, Hawton K, Geulayov G, Waters K, Ness J, Townsend E, Khundakar K, Kapur N. Rates of self-harm presenting to general hospitals: a comparison of data from the Multicentre Study of Self-Harm in England and Hospital Episode Statistics. BMJ open. 2016 Feb 1;6(2):e009749.

3. Welsh Govt New suicide prevention plan to support most vulnerable, 2015 http://www.wales.nhs.uk/news/38065

4. Sinclair JM, Gray A, Rivero-Arias O, Saunders KE, Hawton K. Healthcare and social services resource use and costs of self-harm patients. Social psychiatry and psychiatric epidemiology. 2011 Apr 1;46(4):263-71.

5. Owens D, Horrocks J, House A. Fatal and non-fatal repetition of self-harm. The British Journal of Psychiatry. 2002 Sep 1;181(3):193-9.

6. Gilbody S, House A, Owens D. The early repetition of deliberate self harm. Journal of the Royal College of Physicians of London. 1996 Dec;31(2):171-2.; 31:171–172

7. Hawton K, Bergen H, Cooper J, Turnbull P, Waters K, Ness J, Kapur N. Suicide following self-harm: findings from the Multicentre Study of self-harm in England, 2000–2012. Journal of affective disorders. 2015 Apr 1;175:147-51.

8 . Skegg K. Self-harm. The Lancet. 2005 Oct 28;366(9495):1471-83.

9. Kessler RC, Borges G, Walters EE. Prevalence of and risk factors for lifetime suicide attempts in the National Comorbidity Survey. Archives of general psychiatry. 1999 Jul 1;56(7):617-26.

10. Chartrand H, Bhaskaran J, Sareen J, Katz LY, Bolton JM. Correlates of nonsuicidal self-injury and suicide attempts among tertiary care, emergency department patients. The Canadian Journal of Psychiatry. 2015 Jun 1;60(6):276-83.

11..National Collaborating Centre for Mental Health (UK). Self-Harm: Longer-Term Management. Leicester (UK): British Psychological Society; 2012. (NICE Clinical Guidelines, No. 133.) 7, *Psychological and Psychosocial Interventions*. Available from: http://www.ncbi.nlm.nih.gov/books/NBK126779/

12. Ougrin D, Latif S. Specific psychological treatment versus treatment as usual in adolescents with self-harm. Crisis. 2011 Jan 14.

13. Hepp U, Wittmann L, Schnyder U, Michel K. Psychological and psychosocial interventions after attempted suicide. Crisis. 2004 May;25(3):108-17.

14. National Institute for Clinical Excellence. Self-Harm: The Short Term Physical and Psychological Management and Secondary Prevention of Self-Harm in Primary and Secondary Care. 2004.

15. Cooper J, Steeg S, Bennewith O, Lowe M, Gunnell D, House A, Hawton K, Kapur N. Are hospital services for self-harm getting better? An observational study examining management, service provision and temporal trends in England. BMJ open. 2013 Nov 1;3(11):e003444.

16. Hickey L, Hawton K, Fagg J, Weitzel H. Deliberate self-harm patients who leave the accident and emergency department without a psychiatric assessment: a neglected population at risk of suicide. Journal of psychosomatic research. 2001 Feb 28;50(2):87-93.

17. Kapur N, Steeg S, Webb R, Haigh M, Bergen H, Hawton K, Ness J, Waters K, Cooper J. Does clinical management improve outcomes following self-harm? Results from the multicentre study of self-harm in England. PloS one. 2013 Aug 1;8(8):e70434.

18. Haw C, Hawton K. Life problems and deliberate self-harm: associations with gender, age, suicidal intent and psychiatric and personality disorder. Journal of Affective Disorders. 2008 Jul 31;109(1):139-48.

19. Hawton K, Saunders KE, O'Connor RC. Self-harm and suicide in adolescents. The Lancet. 2012 Jun 29;379(9834):2373-82.

20. Bancroft J, Skrimshire A, Casson J, Harvard-Watts O, Reynolds F. People who deliberately poison or injure themselves: their problems and their contacts with helping agencies. Psychological medicine. 1977 May 1;7(02):289-303.

21. Kposowa AJ. Marital status and suicide in the National Longitudinal Mortality Study. Journal of epidemiology and community health. 2000 Apr 1;54(4):254-61.

22. Barr B, Taylor-Robinson D, Scott-Samuel A, McKee M, Stuckler D. Suicides associated with the 2008-10 economic recession in England: time trend analysis. 2012

23. Stack S. Suicide: a 15-year review of the sociological literature part I: cultural and economic factors. Suicide and Life-Threatening Behavior. 2000 Jun 1;30(2):145-62.

24. Webb L. Deliberate self-harm in adolescence: a systematic review of psychological and psychosocial factors. Journal of advanced nursing. 2002 May 1;38(3):235-44.

25. Hawton K, Witt KG, Salisbury TL, Arensman E, Gunnell D, Hazell P, Townsend E, van Heeringen K. Pharmacological interventions for self-harm in adults. BJPsych Advances. 2016 Jan 1;22(1):2 DOI: 10.1002/14651858.CD011777.

26 Hawton K, Witt KG, Taylor Salisbury TL, Arensman E, Gunnell D, Hazell P, Townsend E, van Heeringen K. Psychosocial interventions for self-harm in adults. The Cochrane Library. 2016 May 12. DOI: 10.1002/14651858.CD012189.

27. Hawton K, Arensman E, Townsend E, Bremner S, Feldman E, Goldney R, Gunnell D, Hazell P, van Heeringen K, House A, Owens D. Deliberate self harm: systematic review of efficacy of psychosocial and pharmacological treatments in preventing repetition. Bmj. 1998 Aug 15;317(7156):441-7.

28. Townsend E, Hawton K, Altman DG, Arensman E, Gunnell D, Hazell P, House A, Van Heeringen K. The efficacy of problem-solving treatments after deliberate self-harm: meta-analysis of randomized controlled trials with respect to depression, hopelessness and improvement in problems. Psychological medicine. 2001 Aug 1;31(06):979-88.

29. De Leo D, Buono MD, Dwyer J. Suicide among the elderly: the long-term impact of a telephone support and assessment intervention in northern Italy. The British Journal of Psychiatry. 2002 Sep 1;181(3):226-9.

30. Milner AJ, Carter G, Pirkis J, Robinson J, Spittal MJ. Letters, green cards, telephone calls and postcards: systematic and meta-analytic review of brief contact interventions for reducing self-harm, suicide attempts and suicide. The British Journal of Psychiatry. 2015 Mar 1;206(3):184-90.

31. Kapur N, Cooper J, Bennewith O, Gunnell D, Hawton K. Postcards, green cards and telephone calls: therapeutic contact with individuals following self-harm. The British Journal of Psychiatry. 2010 Jul 1;197(1):5-7.

32. Chioqueta AP, Stiles TC. The relationship between psychological buffers, hopelessness, and suicidal ideation: identification of protective factors. Crisis. 2007 Jan;28(2):67-73.

33. Petrakis M, Joubert L. A social work contribution to suicide prevention through assertive brief psychotherapy and community linkage: Use of the Manchester Short Assessment of Quality of Life (MANSA). Social work in health care. 2013 Feb 1;52(2-3):239-57.

34. Beck AT, Steer RA, Brown GK. Beck depression inventory-II. San Antonio, TX. 1996:78204-2498.

35. Priebe S, Huxley P, Knight S, Evans S. Application and results of the Manchester Short Assessment of Quality of Life (MANSA). International journal of social psychiatry. 1999 Mar 1;45(1):7-12.

36. Beecham, J., Knapp, M. Costing psychiatric interventions. In: Thornicroft G, ed. Measuring Mental Health Needs, 2nd edn. 2001 London: Gaskell

37. Lyons RA, Jones KH, John G, Brooks CJ, Verplancke JP, Ford DV, Brown G, Leake K. The SAIL databank: linking multiple health and social care datasets. BMC medical informatics and decision making. 2009 Jan 16;9(1):1.

38. Ford DV, Jones KH, Verplancke JP, Lyons RA, John G, Brown G, Brooks CJ, Thompson S, Bodger O, Couch T, Leake K. The SAIL Databank: building a national architecture for e-health research and evaluation. BMC health services research. 2009 Sep 4;9(1):1.

39. Baguley T. Serious stats: A guide to advanced statistics for the behavioral sciences. Palgrave Macmillan; 2012 Jun 26.

40. Frasure-Smith N, Lespérance F, Prince RH, Verrier P, Garber RA, Juneau M, Wolfson C, Bourassa MG. Randomised trial of home-based psychosocial nursing intervention for patients recovering from myocardial infarction. The Lancet. 1997 Aug 16;350(9076):473-9.

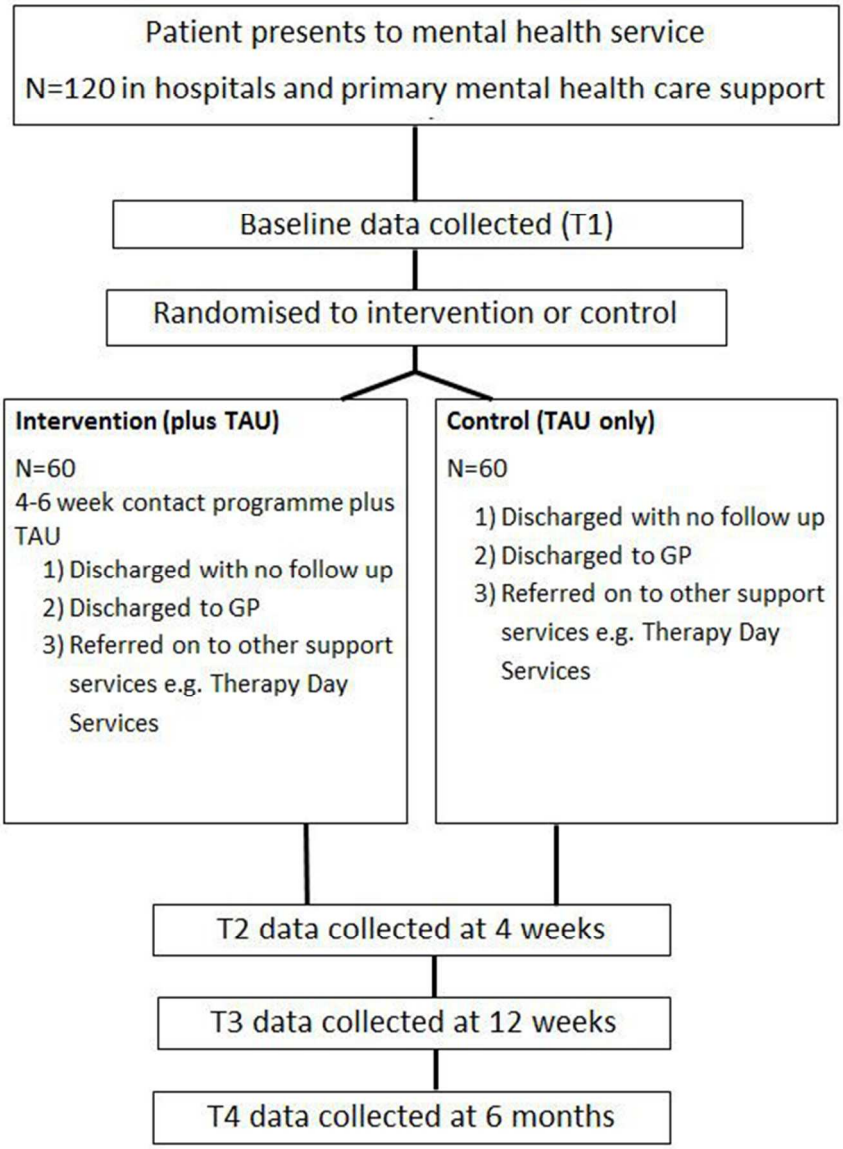
41. Merrill RM. Statistical Methods in Epidemiologic Research. Jones & Bartlett Publishers; 2015 Aug 3.

42. Lindley DV, Scott WF. 1984 New Cambridge Statistical Tables Cambdrige.

43. Schulz KF, Altman DG, Moher D. CONSORT 2010 statement: updated guidelines for reporting parallel group randomised trials. BMC medicine. 2010 Mar 24;8(1):1.

44. Ridyard C, Hughes D. Review of the use of resource use instruments based on patient recall in relation to other methods of resource use estimation. Trials. 2013 Nov 29;14(1):1.

45. Perlman B, Hartman EA, Bosak J. A study of mental health administrators and systems utilizing a four-part rural/urban taxonomy. Community mental health journal. 1984 Sep 1;20(3):202-11.



Study chart
see Figure 1

SPIRIT

STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number of manuscript
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	1, 11
	2b	All items from the World Health Organization Trial Registration Data Set	N/A
Protocol version	3	Date and version identifier	N/A
Funding	4	Sources and types of financial, material, and other support	10
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1
	5b	Name and contact information for the trial sponsor	11
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	N/A
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	9
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each	2-3

		intervention	
	6b	Explanation for choice of comparators	3
Objectives	7	Specific objectives or hypotheses	3
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	3
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	3
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	4
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	4
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	5
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	N/A
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	6
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	3,9
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	8
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	4
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	N/A
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is	4

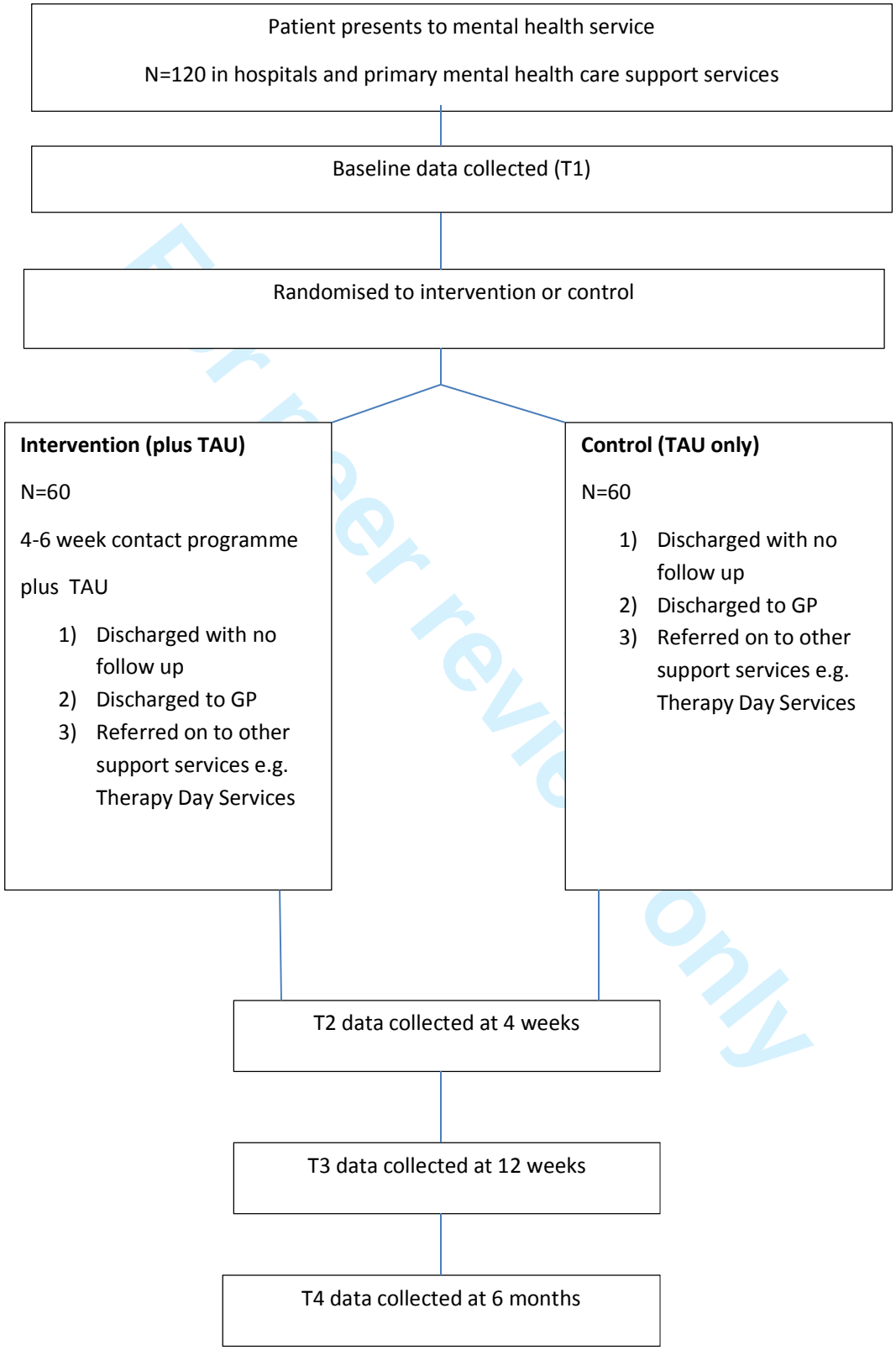
		unavailable to those who enrol participants or assign interventions	
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	4
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	4
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	7
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	N/A
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	6
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	4
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	9
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	9 Contact statistician for more information
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	Contact statistician
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	Contact statistician
Methods: Monitoring			

Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	This is a feasibility study so no formal DMC in place,. However Swansea Trials Unit are managing the data and data is collected in accordance with their regulations
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	N/A
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	N/A
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	None in place formally as this is a feasibility study, but the sponsor has its internal audit process that the trial is subject to.
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	1
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	N/A
Consent or	26a	Who will obtain informed consent or assent from potential trial participants or authorised	3

assent		surrogates, and how (see Item 32)	
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	10
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	N/A
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	N/A
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N/A
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	N/A
	31b	Authorship eligibility guidelines and any intended use of professional writers	N/A
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	N/A
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	attached separately/available from CI
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

Recruitment chart CONSORT statement (NB this chart is included in main document)



BMJ Open

Investigating the feasibility of an enhanced contact intervention in self harm and suicidal behaviour: A protocol for a randomised controlled trial delivering a Social support and Wellbeing Intervention following Self Harm (SWISH)

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2016-012043.R3
Article Type:	Protocol
Date Submitted by the Author:	17-Aug-2016
Complete List of Authors:	Ahmed, Nilufar; Swansea University College of Human and Health Sciences, Public Health, Policy and Social Sciences John, Ann; Swansea University, Farr Institute Islam, Saiful; Swansea University, College of Medicine Jones, Richard; Hywel Dda Health Board Anderson, Pippa; Swansea University, Centre for Health Economics Davies, Charlotte; Hywel Dda Health Board Khanom, Ashrafunnesa; Swansea University, School of Medicine Harris, Shaun; Swansea University, Farr Institute Huxley, Peter; Bangor University
Primary Subject Heading:	Mental health
Secondary Subject Heading:	Health services research, Mental health
Keywords:	randomised controlled trial, self harm, intervention, depression, social support, suicide prevention

Investigating the feasibility of an enhanced contact intervention in self harm and suicidal behaviour: A protocol for a randomised controlled trial delivering a Social support and Wellbeing Intervention following Self Harm (SWISH)

Nilufar Ahmed*[1], Ann John[1], Saiful Islam[1,], Richard Jones[2] , Pippa Anderson[1], Charlotte Davies[2], Ashra Khanom[1], Shaun Harris[1], Peter Huxley[3]

Abstract

Introduction: Self harm is a strong predictor for suicide. Risks for repeat behaviour are heightened in the aftermath of an index episode. There is no consensus on the most effective type of intervention to reduce repetition. Treatment options for patients who do not require secondary mental health services include: no support, discharge to General Practitioner, or referral to primary care mental health support services. The aim of this study is to assess whether it is feasible to deliver a brief intervention after an episode and whether this can reduce depressive symptoms and increase sense of wellbeing for patients who self harm.

Methods: This is a non-blinded parallel group randomised clinical trial. One hundred and twenty patients presenting with self harm and/or suicidal ideation to mental health services over a twelve month period who are not referred to secondary services will be randomised to either intervention plus treatment as usual (TAU), or control (TAU only). Patients are assessed at baseline, 4 weeks and 12 weeks with standardised measures to collect data on depression, wellbeing, and service use. Primary outcome is depression scores; secondary outcomes are wellbeing scores and use of services. The findings will indicate whether a rapid response brief intervention is feasible and can reduce depression and increase wellbeing among patients who self harm and do not require secondary services.

Ethics and dissemination: Ethical approval was granted by the UK National Health Service (NHS) Ethics Committee process (REC 6: 14/WA/0074). The findings of the trial will be disseminated through presentations to the participating Health Board and partners, peer-reviewed journals, national and international conferences.

Trial registration: The trial is registered with the International Standard Randomised Controlled Trial Network (ISRCTN 76914248); and UK Clinical Research Network (16229)

Keywords: Randomised controlled trial, Self Harm, Suicide, Intervention, Social wellbeing, Social support, Social networks, Depression

*Corresponding Author:
Dr Nilufar Ahmed
27 Haldane Building
College of Human and Health Sciences
Swansea University, Singleton Park, Swansea, SA2 8PP
01792 602819
n.ahmed@swansea.ac.uk
[1]Swansea University
[2]Hywel Dda University Health Board
[3]Bangor University

Strengths and limitations of the study

Strengths

- The development of an enhanced contact intervention for people who have little or no support following self harm.
- A focus on social issues that are present in the person's life
- A cost-effective intervention that can work alongside existing services, supporting patients during a vulnerable time and keeping them engaged whilst they are awaiting assessment from other services.
- A strong retention rate for the trial suggests patients are happy to engage with the intervention.
- Patients will be followed up using routine data linkage for long term follow up

Limitations

- Social linkage relies on access to services and transport that can inhibit those without means and access
- As this is an unblinded trial there is a risk of bias in the data
- We are not collecting any social outcome measures

Background

Self-harm is the strongest risk factor for future suicide[1] resulting in over 200,000 hospital presentations annually in England and Wales[2, 3] and is associated with high personal, social and medical costs[4]. Repetition is common, with between 15-25% re-presenting to the same hospital within a year of the index episode.[5] The highest risk of repeat self harm is within 3-6 months after the index episode[6] with the risk for suicide in the year following self harm almost 50 times higher than in the general population.[7]

Depressive symptoms are prevalent amongst those with self harm and suicidal ideation[8] is strongly linked with progression to suicide attempt.[9] Due to the strong link between a mental health condition and self harm,[10] the majority of interventions are based on psychological and medical approaches.[11] However it is not just mental health disorders that trigger self harm, it is known that most patients who present with self harm have numerous social and interpersonal problems which act as catalysts for self harm behaviour.[12,13] Hence NICE guidelines explicitly state that patients who present with self harm should receive a psychosocial assessment[14] to address their psychological and social needs. However ,this is often not routinely offered[15] and many patients who present to the emergency department with self harm are discharged without any assessment[16] despite evidence that psychosocial assessment is associated with a lower risk of repetition.[17] Presentations to hospital tend to prioritise risk factors to determine medical needs, admission, referral, or discharge, above psychosocial needs. A lack of psychosocial assessment leaves much of the impact of social situations under examined. Whilst addressing immediate psychological and medical needs are vital, a lack of exploration of the social milieu of the patient may miss important factors that might have been precipitous in the self harm behaviour and therefore may be a recurring antecedent for self harm. In the absence of routine psychosocial assessments,[15] patients who present with self harm and who do not have a known history of mental health problems, often receive little or no support from health

care services, with signposting to community services or discharge to General Practitioner (GP) being the main course of management. Supporting such individuals who do not require secondary mental health services to deal with stressors and enabling them to better manage stressors may help alleviate their impact and thus reduce rates of self harm as a response to ongoing or repeated stress.

There have been calls to explore social factors when assessing self harm as they are increasingly being identified as instrumental in these behaviourss.[18] Studies report that as many as 70% of self harm episodes are triggered by interpersonal problems.[19] The importance of recognising and responding to social factors in self harm and suicide prevention has been described in the literature.[20] There is global evidence of significant increases in suicide rates following economic recession[21] with unemployment being strongly linked with suicide for men and women.[20] Research has also linked an elevated risk of suicide with isolation and a lack of social integration.[22]

There is little effective primary care prevention for patients who self harm either as a first episode or repeatedly.[23] Numerous interventions have been trialled in attempting to reduce self harm and suicidal behaviour.[24,25] These vary significantly in content, and no single type of intervention has been found to deliver consistent results. Positive outcomes in reducing self harm have been reported for non-pharmacological interventions[26] such as provision of an emergency access card.[27] Findings from contact interventions vary, with some reporting long term positive impacts.[28,29,30,31] Contact interventions, including telephone, postcard and letter interventions offer a cost-effective way of supporting individuals by reducing a sense of isolation and increasing a sense of social connectedness; it has been argued that perceived connectedness can reduce suicidal ideation.[31] An elevated sense of support may encourage help seeking at times of crisis.[31] Reviews of contact-based interventions (e.g. postcards, crisis cards, telephone calls) after admission to hospital have found inconsistent results across studies and concluded that more research is needed.[30,31]

This study draws on findings that suggest increasing social support through contact based interventions can support those who self harm and reduce suicide rates.[29] An Australian study[32] reported an intervention focussing on connecting individuals to relevant and available support led to a reduction in depression scores and an increase in wellbeing. This study adapts that intervention to offer a brief non-psychological and non-medical intervention delivered by trained practitioners. Initially we intended to replicate the study, but a difference in health care systems and access across Australia and the UK, means that a full replication is not possible (see Willis et al.[33] for a description of the Australian healthcare system). In remaining as close to that study we are using the same outcome measures they applied – BDI-II (Beck Depression Inventory – II)[34] to measure depression and MANSA (Manchester Short Assessment of Quality Of Life)[35] to measure quality of life. Additionally we are collecting the CSRI (Client Services Receipt Inventory)[36] to measure service use and the study is registered with the Secure Anonymised Information linkage (SAIL) database for a one year follow up of service use.[37,38]

The aim of this study is to assess whether an enhanced contact intervention is beneficial for patients who present with self harm and/or suicidal ideation but are not referred to secondary services. We define it as an enhanced contact intervention as it goes further than what is usually termed contact intervention in the literature. Contact interventions tend to be more remote and use postcards or phonecalls.[28,29,30] Our intervention involves regular face to face contact. It focuses on social factors and actively links individuals to services that can help with social problems including financial issues, housing, relationship difficulties, employment, literacy etc. The intervention is flexible to meet the needs of the patient; it does not require patients to engage with services if they are not ready; for such patients, regular contact with the intervention practitioner provides support and a source of

social contact at a vulnerable time. The intervention goes beyond signposting with assertively linking the individual to relevant support agencies (e.g. community organisations) that already exist. By doing so, the individual becomes embedded in to a support network which they can draw on at future times of stress.

METHOD

Design and setting

This is a randomised controlled trial (RCT) conducted by Swansea University in partnership with Hywel Dda University Health Board (HDUHB) running between January 2015-March 2016 in Carmarthenshire, West Wales. The trial delivers a brief contact intervention to patients over 18 who present to Mental Health Services (defined as hospital Emergency Department and Local Primary Mental Health Support Services) who would ordinarily be referred back to primary care and/or community services. Patients who require admission or crisis intervention are excluded from SWISH and referred to appropriate services. Patients who meet the inclusion criteria are randomised to the intervention or control group. The intervention is a 4-6 week programme of face to face and phone call contact tailored to meet the needs of the individual in addition to Treatment As Usual (TAU) which ranges from discharge with no further support, signposting via leaflets to community organisations, or referral to primary care for ongoing care. The control arm is just Treatment As Usual. The full duration of patient participation is 12 weeks with assessments collecting standardised measures for depression, wellbeing, and service use conducted for all patients at baseline, 4 weeks and 12 weeks. Where possible a 6 month follow up using the same measures will be sought (see Figure 1).

Study population

Patients who present to Mental Health Services (either directly to hospital, or indirectly through referral from General Practitioner to Local Primary Mental Health Support Services) with self harm and/or suicidal ideation are assessed by Mental Health Practitioners at these sites and those thought suitable for SWISH are referred to SWISH in addition to their treatment as usual. A SWISH worker conducts a further eligibility test based on inclusion and exclusion criteria before inviting a patient who meets the requirements to participate. Patients are given a study information leaflet and time to consider whether they would like to take part. Written consent is obtained by the research assistant prior to baseline data collection. Once baseline data has been collected patients are randomly assigned to either intervention or control.

Inclusion criteria:

Person aged 18 or over who presents to Mental Health Services with self harm and/or suicidal ideation and is assessed by a Mental Health Practitioner at these sites to not require secondary mental health services and be suitable for SWISH.

Exclusion criteria:

Anyone who following assessment by a Mental Health Practitioner, meets at least one of the following criteria:

- unable to give informed consent
- requires admission to a mental health inpatient unit
- requires secondary mental health services
- assessed as high risk for violence

- known or assessed to have a severe mental illness and require other services
- is under a current and active care and treatment plan with Adult Mental Health Services
- is unable to communicate in English

At any point, if a recruited patient meets any of the exclusion criteria they are withdrawn from the study, but their anonymised data will be retained for analysis.

Power and sample size

The power analysis is based on the primary outcome measure, BDI-II score. Based on published reviews and papers, a five to ten percent change in the BDI-II score represents a clinically important difference and the standard deviation varies between 6 to 10 [39,40,41] which provides an effect size of approximately 0.53. To detect a five to ten point difference in the BDI mean score between intervention and the control conditions, with 80% power, requires a sample size of 120 (60 in each arm of the trial).

As this study is assessing feasibility for a full trial of a new intervention, we cannot anticipate the attrition rate, but will use the attrition at 6 and 12 weeks to inform the full trial. For the same reason there are no stopping guidelines, except the complete failure to recruit to the required sample size.

Randomisation

We performed an individual randomisation of the patients from the study population who met the inclusion criteria. As this is a feasibility study we did not use any stratification for randomisation (e.g. stratify between ideators and self harmers). We will be looking at differences during analysis, and should there be any significant differences we intend to incorporate stratification in the future full trial. Patients are randomised after completion of baseline assessment by the Intervention Practitioner using an online randomisation tool managed by Swansea Trials Unit. Patients are randomised with a ratio of 1:1 to intervention and control and used random numbers generated from the *New Cambridge Statistical Table.*[42]

Intervention

The intervention is a 4-6 week enhanced contact programme which is a mix of face to face and telephone contact. It deliberately steers away from being a psychological or medical service; rather it is based on linking individuals into social support networks and encouraging access to, and engagement with, relevant services. It is an additional rather than alternative service for support services already in place, and encourages patients to engage with existing services. As such, as long as patients are not receiving support from secondary mental health services (an exclusion criteria based on higher support needs of secondary mental health service users); there is no contraindication to involvement with SWISH.

An awareness of local third sector services is key to the role of the practitioner. The intervention can be delivered by a skilled individual who has experience of working with people with mental health issues. The practitioners delivering the intervention in this trial have worked in mental health services but are not registered mental health practitioners. They have experience of working in Carmarthenshire within mental health services and/or developing mental health services for vulnerable populations. By not requiring practitioners to hold registrations, the intervention is more cost effective to deliver as it relies on locality-based training and awareness above registration. A

condition of employment is to have enhanced Disclosure and Barring Service clearance before commencement. The practitioners receive training on mental health service delivery in Carmarthenshire from an Advanced Nurse Practitioner in mental health services. Formal clinical supervision with the Advanced Nurse Practitioner is once a fortnight or more depending on requirements; the supervisor is available at all times on the phone for immediate questions, and monitors the delivery of the intervention and patient contact.

The intervention encourages individuals to link with local services. In this trial some of the agencies patients are linked into include Men's Shed projects, adult education courses, knitting groups and volunteering services; as well as services supporting individuals with drug and alcohol issues and domestic abuse. The choice of service is decided alongside the patient based on the type of support and engagement they would like. The intervention primarily focuses on the social dimensions of a person's life; the medical and psychological needs of the patient will have been assessed prior to the patient's referral to SWISH. If at any time during the intervention the practitioner is concerned that these needs may be escalating and require specialised support, or there is a crisis situation this will be immediately discussed with the clinical supervisor who will refer the patient accordingly; and SWISH will continue to support the patient for the duration of the intervention, or until they meet the exclusion criteria and are engaged with relevant support services.

The first patient-practitioner contact is as soon as possible after baseline has been collected by a research assistant. At the first meeting the patient is encouraged to discuss recent events and explore the reasons which they feel led to their current situation. This meeting typically lasts about an hour. The practitioner works with the patient to identify the main social issues they feel precipitated this and they discuss relevant agencies that may be able to offer support and information. A plan of action is then worked out with the patient where the patient is given suggestions for services that they can link in with. This plan is written up by the practitioner and sent to the patient with information and contact details for services.

Treatment as usual for patients with low or no mental health history who present to the hospital Emergency Department is usually referral back to GP; although some might be signposted to services in the community usually by way of leaflets provided. Treatment as usual for patients referred by their GP to Local Primary Mental Health Support Services, is an assessment within 4-8 weeks and appropriate referral or signposting. This intervention goes beyond signposting to assertively link the patient with relevant services to embed them within a supportive network at a time of emergency and vulnerability to try and ameliorate the negative impact of the self harm episode. This 'assertive community linkage' is the basis for the intervention. It differs from signposting by actively encouraging patients to contact relevant community agencies who can provide specialised support and establish a supportive resource to help manage future periods of stress. The practitioner can follow up whether they have made contact with any agencies and explore reasons for reluctance to engage. Where necessary, the practitioner can make a referral or initiate contact and support for patients, for example one patient was keen to attend a local craft group but felt scared to attend alone, the practitioner made contact with the service and arranged for the patient to meet with the craft group co-ordinator alone prior to attending the group to discuss her fears and be reassured.

Follow up contacts are a mix of face to face and telephone contacts depending on agreement and discussion with patient. Patients are seen at a location that is convenient to them, this includes home visits, however as part of the community linkage patients are encouraged to engage outside of the home and so meetings are held in local spaces including GP surgeries, coffee shops and arts centres. This is especially the case for patients who do not feel confident or willing to actively engage with available social networks or for whom there is not a local service that suits their needs. In such

instances, the practitioner provides a purely contact and listening service, encouraging the patient to leave the house and meet for a chat. Details of all contacts are logged on the FACE electronic recording system used by Hywel Dda University Health Board as their health care notes recording system. The number and nature (face to face or telephone) and length of contacts vary depending on patient need and are mutually decided between patient and practitioner. The minimum number is four and the maximum is usually six, with the first and final contact always being face to face. As this is a feasibility study we have been flexible with the final number of sessions to accommodate patients who may be waiting for another service. In this situation SWISH provides support until they are engaged with another provider. This has resulted in up to eight sessions in three cases.

This is an important feature of the intervention where as well as providing a stand-alone service linking individuals to community services it acts as a bridging service for patients. Patients referred to Local Primary Mental Health Support Services and those who have been referred to other (non-secondary) mental health support services such as psychological therapy services typically face a 4-8 week wait for assessment. The intervention provides a point of regular contact and support during this waiting period.

Control

The control group receive treatment as usual from the service they presented to. This ranges from no action, discharge to GP, signposting to community services and/or referral to psychological therapy services. These treatments do not conflict with SWISH.

Outcome measures

The primary outcome measure is the BDI-II, measuring depressive symptoms as this was the primary outcome measure in the Australian study. For the same reason our secondary outcome assesses whether a social intervention leads to overall increase in wellbeing, as measured by the MANSA. Additionally we are collecting data on whether the intervention reduces rates of representation to mental health services as measured by the CSRI and long term follow up of service use by SAIL.

Our choice of primary and secondary outcomes is based on remaining as close to the Australian study as possible based on the information available. For a further trial we will seek to collect data on social outcomes, exploring the type and nature of social networks that individuals engage with as an outcome of the intervention.

Assessments

All patients complete assessments at baseline (before randomisation), 4 weeks and 12 weeks. Those who fall in to the six month period whilst the study is running are invited to complete a 6 month assessment. A one year follow up will be conducted by SAIL.

Baseline assessments

The baseline assessment consists of the BDI-II, MANSA and CSRI. Patients are asked to complete these questionnaires as soon as possible after they consent. The questionnaires are designed to be

self-completed, however the researchers read out the questions and fill in the responses where requested by patients. Researchers note whether they are required to read out any/all questions, and any questions patients have asked for clarity or elaborated upon while completing the questionnaire pack. Patients are given a £10 voucher for their time after completing the baseline assessment. All contact with patients is recorded on the health board electronic patient contact recording system.

Follow up assessments

4 week follow up

Follow up assessments are conducted with the same questionnaires (BDI-II, MANSA, CSRI) at 4 weeks. Patients are given no incentive at the 4 week assessment. 12 week follow up

Patients are asked to complete the BDI-II, MANSA and CSRI. Patients who complete the 12 week assessment are given a £20 voucher for their time.

Additionally at the 12 week data collection patients are asked to complete an evaluation form of their experience of SWISH. There is room for additional comments. The researcher asks for the feedback on the contact and this is recorded verbatim for qualitative analysis, and to provide assessment of the service in the patient's own words. Initially this data was only included for intervention patients, however we have begun to collect it for control as well after control patients commented on the support they felt they were receiving from the researcher collecting assessment data.

Six month follow up

Early recruits are invited to take part in a 6 month assessment where possible, and a further £10 voucher is given for their time.

One year follow up

Patients have consented to being linked in anonymously to the SAIL Databank (http://www.saildatabank.com/). SAIL contain routinely collected anonymous data for Wales. We will use the SAIL data for the number of visits (or contacts) to primary (General Practitioner) and secondary care (Hospital admission and Emergency Department visit) by the SWISH patients for the year preceding and the year following the intervention. We will be collecting the counts of contacts that relate to self-harm, suicidal ideation and depression.

Blinding

There is no blinding of researchers or participants. The information sheet clearly states the intervention is a 4-6 week contact programme. The researcher advises all patients that the intervention practitioner will be in touch within a few days if they are randomised to the intervention. It has proved impractical and almost impossible to blind the researcher conducting the assessments as at the week four assessment there is often a clash with intervention meetings for the patient. It would be preferable for all assessments to be collected by the researcher, however due to staffing issues in this trial and to minimise the time commitment on the part of the patient and maximise data collection, intervention patients are given the option to complete the 4 week assessment at an intervention meeting with the practitioner rather than the researcher. Some intervention patients prefer just to have one SWISH contact at the 4 week stage rather than find

time for separate meetings with practitioner and researcher. The intervention always includes a discussion of how they are feeling and their social connectedness, so the administration of the questionnaire at the time of intervention avoids some repetition on the part of the patient where the questionnaire is being read to them. However, the majority of questionnaires are completed by respondents individually and put into an envelope after completion, so the practitioner is unaware of their responses. We acknowledge that this might introduce some bias into the methodology; but for a feasibility study and due to the reasons outlined above, we feel that maximum data return should be prioritised.

Trial Management Group

A Trial Management Group whose members include study applicants (academics and health board practitioners), service users, and representatives of community organisations meets once a quarter to monitor progress and discuss any issues arising. The Chief Investigator also attends a monthly Trial Managers meeting at the Swansea Trials Unit to update on progress and discuss the project.

Analysis

Statistical analysis

Our analysis will be based on the primary and secondary outcome measures which are the BDI-II score and MANSA and CSRI. The hypothesis of interest is that the change scores on these outcome measures will be significantly different in the intervention group compared to the control group. We will analyse changes in all outcome measures between baseline and follow-up at 4 weeks, 12 weeks and (where collected) 6 months by adopting repeated measures analysis of variance. We shall use the pertaining values of the outcome measure under analysis and consider participants' demographic characteristics (e.g. age, marital status, sex education level) as covariates. Since both the BDI-II score and MANSA are well validated and use outcome measures respectively for depression and 'Quality of Life', they do not require checking of internal consistency.

As described above, we will be using SAIL to compare the number of contacts to primary and secondary care made by the SWISH participants before and after the intervention between the case and control group. We will use t-tests to assess any differences between the groups.

We will adopt the intention-to-treat (ITT) population, consisting of all subjects randomly assigned to the intervention and control. To deal with the missing values, we shall summarise the frequency of missing data for each variable, which affects effective sample size and hence statistical power. If there is no reason to suspect that data are not Missing Completely At Random (MCAR), we shall consider the use appropriate imputation methods to ameliorate the problem of missing data; otherwise, the Trial Statistician and Chief Investigator will further discuss patterns in missing data. Outcome descriptions, summaries and comparisons will be expressed in accordance with appropriate CONSORT guidelines,[43] including estimates with 95% confidence intervals to summarise two-tailed tests at the 5% significance level.

Health Economics

Health service resource use in primary care, secondary care and the community is collected using the CSRI from participants in both arms of the trial at baseline, 4 weeks, 12 weeks and 6 months. Questions will relate to all health service contacts (hospital appointments, hospital stays, GP contacts, visiting nurse appointments, etc.) and prescription medicines dispensed during the trial period. Patient recall has been shown to be a valid method for collecting health service resource

use data over this period (and, as clinical records are often fragmented, and sometimes unavailable, across different parts of the health service) patient-reported data is likely to remain more readily available and less costly to collect for research purposes.[44] A descriptive analysis of CSRI data, along with estimates of the cost of providing the intervention, will provide a comparison of participant resource use between intervention and control groups, and will provide indicators of the main resource use (and associated costs) drivers of those receiving the intervention.

The CSRI data will be summarised and presented descriptively. The resources utilised and associated costs will be summarised. The costs of the intervention will be estimated. These data will be used to compare the costs of the intervention and usual care and to inform the calculation of incremental costs. The sources of costs will be fully referenced to aid transparency of the analysis. Where possible, published unit costs will be used (e.g. PSSRU Costs of Health and Social Care, British National Formulary, NHS reference costs) using the most recent published sources - 2014/15. Costs (mean and SD and/or 95% confidence intervals or non-parametric equivalent (median and IQRs) will be presented.

Dissemination

Findings will be fed back to the Health Board and to the third sector through presentations and contributions in local publications. Outcomes will be published in peer- reviewed journals and at national and international conferences

DISCUSSION

This paper describes the study protocol for a feasibility study for a randomised controlled trial of an enhanced contact intervention for people who present with self harm or suicidal ideation and do not require secondary mental health services.

Several limitations apply to this study. Firstly, interventions tend to have a high attrition rate. Dropout can introduce a selection bias and pose a threat to validity. However, we are able to report a high rate of recruitment at a 100% of our target and successful intervention completion at 77% across the whole sample. If those who were withdrawn from the study (due to meeting exclusion criteria) are excluded, the completion rate for all those eligible to complete the intervention rises to 83%.

Secondly, the services that SWISH is able to provide are limited. Encouraging social linkage is largely dependent on the availability of relevant options for individuals. In a large, predominantly rural county,[45] there are limited choices, which are further reduced if there is no access to transport. A social linkage programme will be able to offer more resources in areas where there are more agencies and community services to engage with. The location and accessibility of services may affect the generalisability of findings to urban populations.

Thirdly, whilst the assessments are intended to be self-completed, a lack of confidence on the part of patients in completing questionnaires themselves, meant that a substantial number were read out by the researcher. This may have affected responses.

Finally, as discussed above, the study was conducted unblinded. Attempts were made to blind the researcher collecting assessments, however this was not practical.

However, even with limitations, the findings will offer an insight in to the applicability of a social intervention to sit alongside medical and psychological interventions. SWISH offers a short term crisis response to engage patients whilst they are waiting for referrals to medical and community services. Often there are 4-8 week waiting lists to be seen by other services. SWISH fills this void and at the very least it offers a contact and listening service to individuals at a vulnerable time. By engaging with patients whilst they are waiting for other appointments it can help reduce rates not attending appointments with other health and social care services by encouraging attendance. Through embedding patients in to existing local organisations and services, SWISH helps to provide a source of support for future stressful times.

TRIAL STATUS

In follow up period of data collection.

FUNDING AND REGISTRATION

The trial is funded by Health and Care Research Wales and sponsored by Swansea University. The trial is registered with the International Standard Randomised Controlled Trial Network (ISRCTN 76914248); and the UK Clinical Research Network (16229)

AUTHOR CONTRIBUTIONS

NA is Chief Investigator and drafted the protocol, designed the study and organised and supervised implementation. PH conceived the study in conjunction with RJ and AJ; AJ and PH provide methodological expertise. SI is trial statistician and developed the statistical analysis strategy. RJ is clinical supervisor and provides expertise and supervision to practitioners. PA and SH developed the health economics strategy. AK and CD worked on the data collection and data management. NA, AJ and SI worked on the preparation of this manuscript, and all authors provided comments on drafts and approved the final version.

COMPETING INTERESTS

None.

References

1. Cavanagh JT, Carson AJ, Sharpe M, Lawrie SM. Psychological autopsy studies of suicide: a systematic review. Psychological medicine. 2003 Apr 1;33(03):395-405.

2. Clements C, Turnbull P, Hawton K, Geulayov G, Waters K, Ness J, Townsend E, Khundakar K, Kapur N. Rates of self-harm presenting to general hospitals: a comparison of data from the Multicentre Study of Self-Harm in England and Hospital Episode Statistics. BMJ open. 2016 Feb 1;6(2):e009749.

3. Welsh Govt New suicide prevention plan to support most vulnerable, 2015 http://www.wales.nhs.uk/news/38065

4. Sinclair JM, Gray A, Rivero-Arias O, Saunders KE, Hawton K. Healthcare and social services resource use and costs of self-harm patients. Social psychiatry and psychiatric epidemiology. 2011 Apr 1;46(4):263-71.

5. Owens D, Horrocks J, House A. Fatal and non-fatal repetition of self-harm. The British Journal of Psychiatry. 2002 Sep 1;181(3):193-9.

6. Gilbody S, House A, Owens D. The early repetition of deliberate self harm. Journal of the Royal College of Physicians of London. 1996 Dec;31(2):171-2.; 31:171–172

7. Hawton K, Bergen H, Cooper J, Turnbull P, Waters K, Ness J, Kapur N. Suicide following self-harm: findings from the Multicentre Study of self-harm in England, 2000–2012. Journal of affective disorders. 2015 Apr 1;175:147-51.

8 . Skegg K. Self-harm. The Lancet. 2005 Oct 28;366(9495):1471-83.

9. Kessler RC, Borges G, Walters EE. Prevalence of and risk factors for lifetime suicide attempts in the National Comorbidity Survey. Archives of general psychiatry. 1999 Jul 1;56(7):617-26.

10. Chartrand H, Bhaskaran J, Sareen J, Katz LY, Bolton JM. Correlates of nonsuicidal self-injury and suicide attempts among tertiary care, emergency department patients. The Canadian Journal of Psychiatry. 2015 Jun 1;60(6):276-83.

11..National Collaborating Centre for Mental Health (UK). Self-Harm: Longer-Term Management. Leicester (UK): British Psychological Society; 2012. (NICE Clinical Guidelines, No. 133.) 7, *Psychological and Psychosocial Interventions*. Available from: http://www.ncbi.nlm.nih.gov/books/NBK126779/

12. Hepp U, Wittmann L, Schnyder U, Michel K. Psychological and psychosocial interventions after attempted suicide. Crisis. 2004 May;25(3):108-17.

13. Haw C, Hawton K. Life problems and deliberate self-harm: associations with gender, age, suicidal intent and psychiatric and personality disorder. Journal of Affective Disorders. 2008 Jul 31;109(1):139-48.

14. National Institute for Clinical Excellence. Self-Harm: The Short Term Physical and Psychological Management and Secondary Prevention of Self-Harm in Primary and Secondary Care. 2004.

15. Cooper J, Steeg S, Bennewith O, Lowe M, Gunnell D, House A, Hawton K, Kapur N. Are hospital services for self-harm getting better? An observational study examining management, service provision and temporal trends in England. BMJ open. 2013 Nov 1;3(11):e003444.

16. Hickey L, Hawton K, Fagg J, Weitzel H. Deliberate self-harm patients who leave the accident and emergency department without a psychiatric assessment: a neglected population at risk of suicide. Journal of psychosomatic research. 2001 Feb 28;50(2):87-93.

17. Kapur N, Steeg S, Webb R, Haigh M, Bergen H, Hawton K, Ness J, Waters K, Cooper J. Does clinical management improve outcomes following self-harm? Results from the multicentre study of self-harm in England. PloS one. 2013 Aug 1;8(8):e70434.

18. Hawton K, Saunders KE, O'Connor RC. Self-harm and suicide in adolescents. The Lancet. 2012 Jun 29;379(9834):2373-82.

19. Bancroft J, Skrimshire A, Casson J, Harvard-Watts O, Reynolds F. People who deliberately poison or injure themselves: their problems and their contacts with helping agencies. Psychological medicine. 1977 May 1;7(02):289-303.

20. Kposowa AJ. Marital status and suicide in the National Longitudinal Mortality Study. Journal of epidemiology and community health. 2000 Apr 1;54(4):254-61.

21. Barr B, Taylor-Robinson D, Scott-Samuel A, McKee M, Stuckler D. Suicides associated with the 2008-10 economic recession in England: time trend analysis. 2012

22. Stack S. Suicide: a 15-year review of the sociological literature part I: cultural and economic factors. Suicide and Life-Threatening Behavior. 2000 Jun 1;30(2):145-62.

23. Webb L. Deliberate self-harm in adolescence: a systematic review of psychological and psychosocial factors. Journal of advanced nursing. 2002 May 1;38(3):235-44.

24. Hawton K, Witt KG, Salisbury TL, Arensman E, Gunnell D, Hazell P, Townsend E, van Heeringen K. Pharmacological interventions for self-harm in adults. BJPsych Advances. 2016 Jan 1;22(1):2 DOI: 10.1002/14651858.CD011777.

25. Hawton K, Witt KG, Taylor Salisbury TL, Arensman E, Gunnell D, Hazell P, Townsend E, van Heeringen K. Psychosocial interventions for self-harm in adults. The Cochrane Library. 2016 May 12. DOI: 10.1002/14651858.CD012189.

26 Hawton K, Arensman E, Townsend E, Bremner S, Feldman E, Goldney R, Gunnell D, Hazell P, van Heeringen K, House A, Owens D. Deliberate self harm: systematic review of efficacy of psychosocial and pharmacological treatments in preventing repetition. Bmj. 1998 Aug 15;317(7156):441-7.

27. Townsend E, Hawton K, Altman DG, Arensman E, Gunnell D, Hazell P, House A, Van Heeringen K. The efficacy of problem-solving treatments after deliberate self-harm: meta-analysis of randomized controlled trials with respect to depression, hopelessness and improvement in problems. Psychological medicine. 2001 Aug 1;31(06):979-88.

28. De Leo D, Buono MD, Dwyer J. Suicide among the elderly: the long-term impact of a telephone support and assessment intervention in northern Italy. The British Journal of Psychiatry. 2002 Sep 1;181(3):226-9.

29. Milner AJ, Carter G, Pirkis J, Robinson J, Spittal MJ. Letters, green cards, telephone calls and postcards: systematic and meta-analytic review of brief contact interventions for reducing self-harm, suicide attempts and suicide. The British Journal of Psychiatry. 2015 Mar 1;206(3):184-90.

30. . Kapur N, Cooper J, Bennewith O, Gunnell D, Hawton K. Postcards, green cards and telephone calls: therapeutic contact with individuals following self-harm. The British Journal of Psychiatry. 2010 Jul 1;197(1):5-7.

31 Chioqueta AP, Stiles TC. The relationship between psychological buffers, hopelessness, and suicidal ideation: identification of protective factors. Crisis. 2007 Jan;28(2):67-73.

32. Petrakis M, Joubert L. A social work contribution to suicide prevention through assertive brief psychotherapy and community linkage: Use of the Manchester Short Assessment of Quality of Life (MANSA). Social Work in Health Care. 2013 Feb 1;52(2-3):239-57.

33. Willis, E., Reynolds, L., & Keleher, H. (Eds.). (2016). Understanding the Australian health care system. Elsevier Health Sciences.

34. Beck AT, Steer RA, Brown GK. Beck depression inventory-II. San Antonio, TX. 1996:78204-2498.

35. Priebe S, Huxley P, Knight S, Evans S. Application and results of the Manchester Short Assessment of Quality of Life (MANSA). International Journal of Social Psychiatry. 1999 Mar 1;45(1):7-12.

36. Beecham, J., Knapp, M. Costing psychiatric interventions. In: Thornicroft G, ed. Measuring Mental Health Needs, 2nd edn. 2001 London: Gaskell

37. Lyons RA, Jones KH, John G, Brooks CJ, Verplancke JP, Ford DV, Brown G, Leake K. The SAIL databank: linking multiple health and social care datasets. BMC medical informatics and decision making. 2009 Jan 16;9(1):1.

38. Ford DV, Jones KH, Verplancke JP, Lyons RA, John G, Brown G, Brooks CJ, Thompson S, Bodger O, Couch T, Leake K. The SAIL Databank: building a national architecture for e-health research and evaluation. BMC health services research. 2009 Sep 4;9(1):1.

39. Baguley T. Serious stats: A guide to advanced statistics for the behavioral sciences. Palgrave Macmillan; 2012 Jun 26.

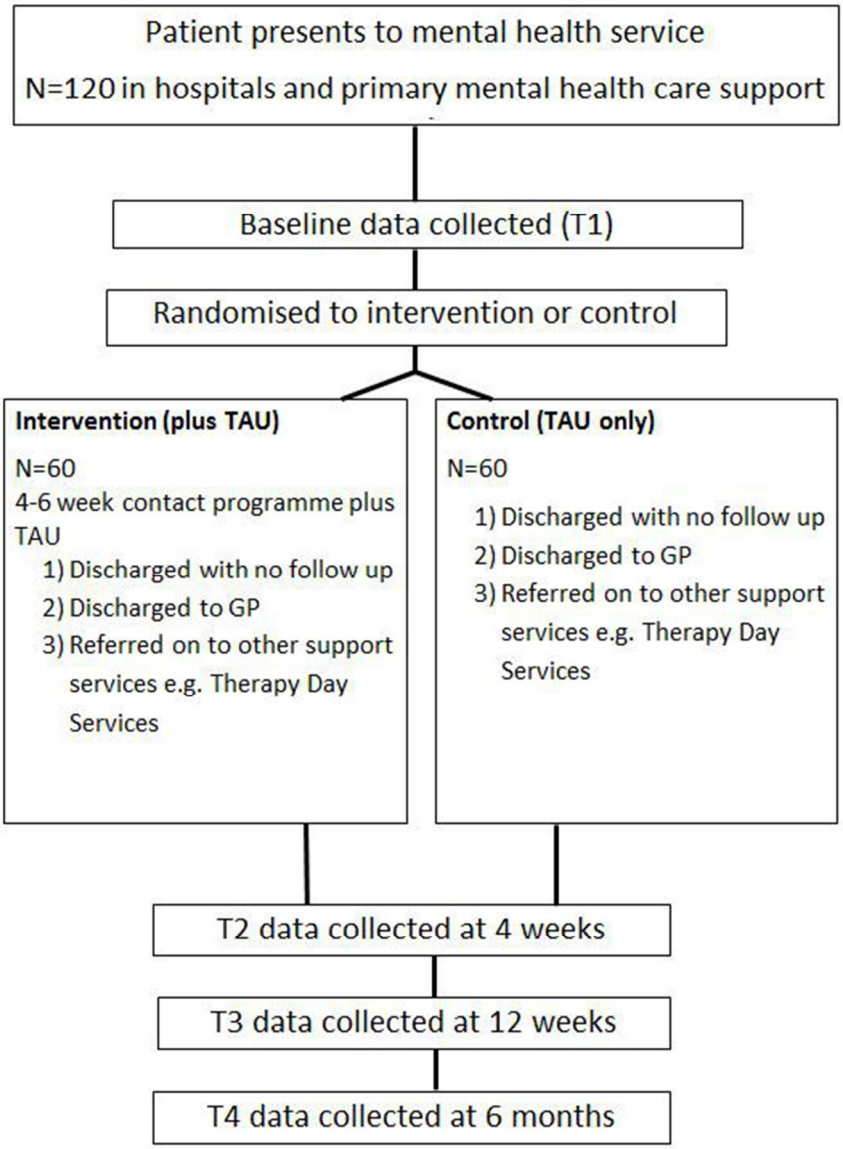
40. Frasure-Smith N, Lespérance F, Prince RH, Verrier P, Garber RA, Juneau M, Wolfson C, Bourassa MG. Randomised trial of home-based psychosocial nursing intervention for patients recovering from myocardial infarction. The Lancet. 1997 Aug 16;350(9076):473-9.

41. Merrill RM. Statistical Methods in Epidemiologic Research. Jones & Bartlett Publishers; 2015 42. Lindley DV, Scott WF. 1984 New Cambridge Statistical Tables Cambdrige.

43. Schulz KF, Altman DG, Moher D. CONSORT 2010 statement: updated guidelines for reporting parallel group randomised trials. BMC medicine. 2010 Mar 24;8(1):1.

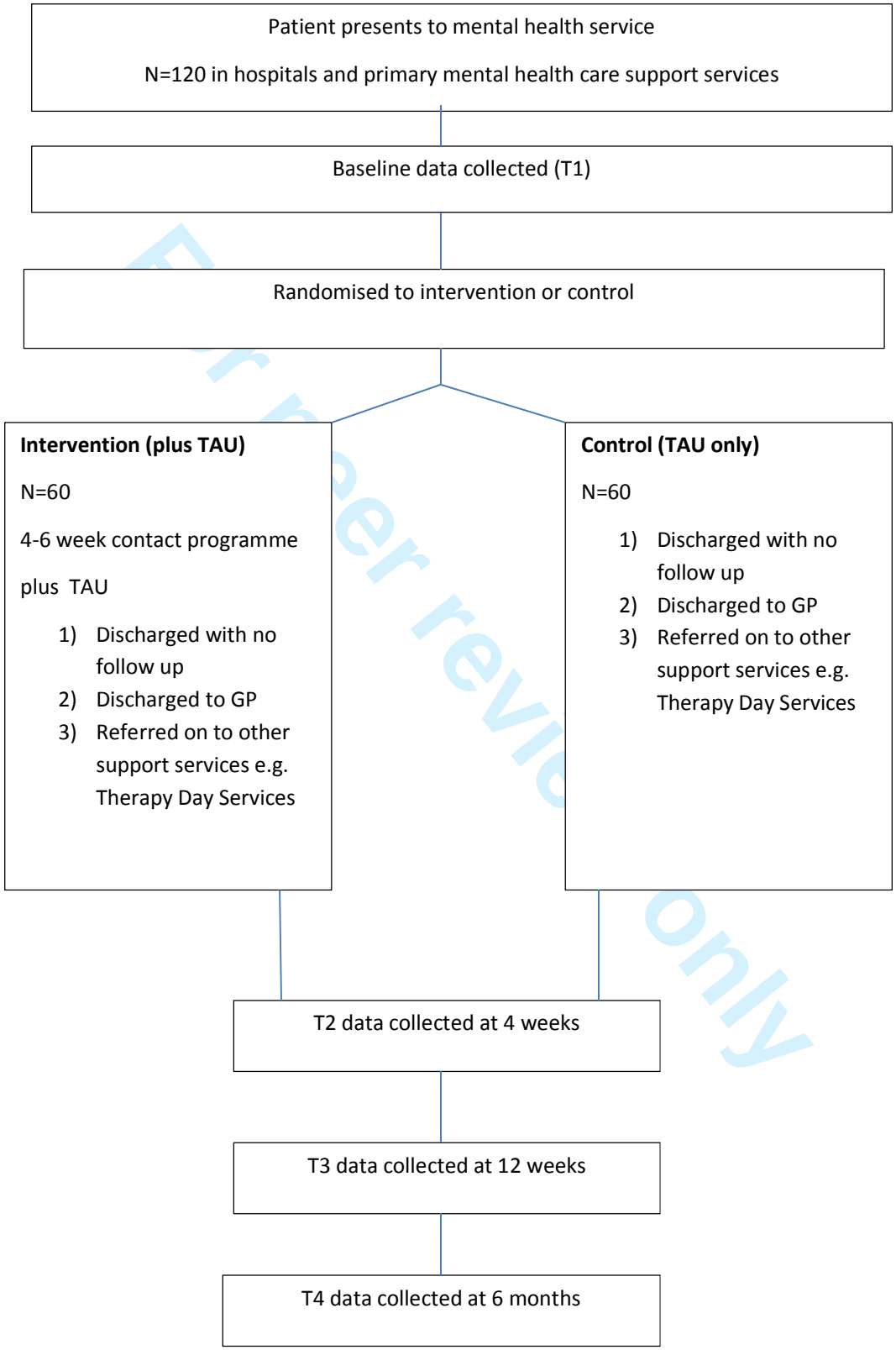
44. Ridyard C, Hughes D. Review of the use of resource use instruments based on patient recall in relation to other methods of resource use estimation. Trials. 2013 Nov 29;14(1):1.

45. Perlman B, Hartman EA, Bosak J. A study of mental health administrators and systems utilizing a four-part rural/urban taxonomy. Community mental health journal. 1984 Sep 1;20(3):202-11.



Study chart
see Figure 1

Recruitment chart CONSORT statement (NB this chart is included in main document)



SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number of manuscript
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	1, 11
	2b	All items from the World Health Organization Trial Registration Data Set	N/A
Protocol version	3	Date and version identifier	N/A
Funding	4	Sources and types of financial, material, and other support	10
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1
	5b	Name and contact information for the trial sponsor	11
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	N/A
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	9
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each	2-3

		intervention	
	6b	Explanation for choice of comparators	3
Objectives	7	Specific objectives or hypotheses	3
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	3
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	3
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	4
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	4
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	5
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	N/A
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	6
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	3,9
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	8
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	4
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	N/A
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is	4

		unavailable to those who enrol participants or assign interventions	
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	4
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	4
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	7
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	N/A
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	6
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	4
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	9
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	9 Contact statistician for more information
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	Contact statistician
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	Contact statistician
Methods: Monitoring			

Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	This is a feasibility study so no formal DMC in place,. However Swansea Trials Unit are managing the data and data is collected in accordance with their regulations
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	N/A
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	N/A
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	None in place formally as this is a feasibility study, but the sponsor has its internal audit process that the trial is subject to.
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	1
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	N/A
Consent or	26a	Who will obtain informed consent or assent from potential trial participants or authorised	3

assent		surrogates, and how (see Item 32)	
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	10
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	N/A
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	N/A
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N/A
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	N/A
	31b	Authorship eligibility guidelines and any intended use of professional writers	N/A
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	N/A
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	attached separately/available from CI
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.