Study design and outcome measures used in evaluation studies of hospital-presenting self-harm: a methodological systematic review **[Data Extraction Form]**

Item
Publication data
Author
Year of publication
Article title
Study characteristics
Study aim
Data source *(standalone research project or name data system used if it is registry/ surveillance system (e.g. multicentre study of self-harm; National Self-Harm Registry Ireland))*
Definition of self-harm used
Geographic setting (country)
Number of sites (/hospitals) included
Study time period
Population (description)
Emergency Department attendance or admission type
- All ED attendances and admissions
- Admissions (discharges) only
- ED attendances only
Inclusion criteria
Exclusion criteria
Sample size
If different sample size used in analyses, please give details
Participant characteristics
Age
Gender
Methods of self-harm
Psychiatric diagnosis
Sociodemographic information/socioeconomic status
Previous self-harm (i.e. at study inception, was previous self-harm reported in the sample?)
Study design
Is this study a *RCT?*
- Randomised
- Non-randomised
Does this study utilise a quasi-experimental design?
- Controlled before-and-after study
- Interrupted time series study
Was there a control/comparison group used?
Details of control/comparison group(s)
Does this study utilise an observational design?
- Before-and-after study (not controlled)
- Interrupted time series study
- Cohort study – prospective
- Cohort study – retrospective
- Case-control study – prospective
- Case-control study – retrospective
- Other (please state)

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Follow up time
Unit of data
- Individual
- Aggregate
- Both
Is this an interventional study? (y/n) *(i.e. experimental (and quasi-experimental) studies where* ***the researcher intervenes during the study period****, including randomised and non-randomised studies, and controlled before-and-after or interrupted time series studies.)*
Is this an observational study? (y/n) *(i.e. all study designs where* ***the researchers <u>are not</u> acting upon the study participants, but observing relationships between factors and outcomes****. These include non-controlled before-and-after studies and interrupted time series studies, cohort and case-control studies)*
Evidence for intervention *(i.e. Did the study find that the intervention was effective? Report impact if possible (e.g. x% reduction in repeat self-harm).)*
NAME: Brief name or a phrase that describes the intervention
WHY: Describe any rationale, theory, or goal of the elements essential to the intervention. (If established part of clinical care, state this here.)
Was the intervention designed by the researchers or simply observed by the researchers (i.e. part of clinical care)?
WHAT: Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (e.g. online appendix, URL).
WHAT: Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities.
WHO PROVIDED: For each category of intervention provider (e.g. psychologist, nursing assistant), describe their expertise, background and any specific training given.
HOW: Describe the modes of delivery (e.g. face-to-face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group.
WHERE: Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features.
WHEN and HOW MUCH: Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose.

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For studies looking at a once off exposure (e.g. assessment/service change), state the time period in which the exposure was measured for (e.g. what period assessments were examined for, or in the case of a service change, what was the period of intervention examined).
Core Outcomes Reporting Quality Checklist
1. Is the primary outcome clearly stated?
2. Is the primary outcome clearly defined so that another researcher would be able to reproduce its measurement? (e.g. time points, person measuring outcome, measurement tools, location of outcome measurement)
3. Are secondary outcomes clearly stated?
4. Are the secondary outcomes clearly defined?
5. Do the authors explain the use of the outcomes they have selected?
Outcomes (adapted from Cochrane data extraction template)
Primary outcome (first mentioned if not identified)
Secondary outcome
Were multiple outcomes used? *If so, how many outcomes were used?*
Were control measures used? *If so, how many control measures were used?*
Complete the following set of items separately for each outcome reported
OUTCOME 1 *Outcome name*
What category best describes OUTCOME 1? [EPOC Resources]
Patient outcomes *(Health status and wellbeing, including: Physical health and treatment outcomes: mortality, morbidity, surrogate physiological measures; Psychological health: psychological wellbeing; Psychosocial outcomes: quality of life, social activities; Health behaviour, e.g. adherence to treatment or care plans, health care seeking behaviour*
Quality of care *(Adherence to recommended practice or guidelines, e.g. extent to which health care providers gave specific advice, delivered specific interventions, followed referral guidelines)*
Utilisation, coverage or access *(Utilisation of services, e.g. length of stay in a facility; Coverage, e.g. proportion patients who received care; enrolment to insurance programmes; Access to services, e.g. waiting times to see a doctor; recruitment and retention of health* *care providers)*
Resource use *(Healthcare resources, e.g. human resources/time, consumable supplies, buildings, equipment; Non-healthcare resources, e.g. transportation to healthcare facilities, social services; Patient and informal caregiver time)*
Health care provider outcomes *(Workload; Work morale; Stress, burnout, sick leave)*
Social outcomes *(Community empowerment or participation; Poverty measures; Employment; Education)*

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Equity* *(differential effects across advantaged and disadvantaged populations)* *this needs to be considered for all of the other outcomes on this list
Adverse effects or harms *(including adverse effects on: Health or health behaviours (e.g. sepsis, the need for caesarean section); Utilisation, coverage or access; Quality of care; Resource use; Health care providers (e.g. increased attrition, increased workload); Social outcomes; Equity (i.e. increased inequities); Clinical adverse effects, e.g. sepsis, the need for caesarean section).*
OUTCOME 1 *What time points were measured* *(specify whether from start or end of intervention)*
OUTCOME 1 *Number of time points reported*
OUTCOME 1 *Outcome definition*
OUTCOME 1 *Source of data*
- Patient self-report
- Clinician interview/questionnaire
- Hospital records
- Other (give details)
Type of data used for OUTCOME 1
- Continuous *(where each individual's outcome is a measurement of a numerical quantity)*
- Categorical/Binary *(where each individual's outcome is one of only two possible categorical responses)*
- Counts/Proportions *(calculated from counting the number of events that each individual experience)*
- Rates *(calculated from counting the number of events experienced using population data)*
- Time-to-event *(data (typically survival data) that analyse the time until an event occurs, but where not all individuals in the study experience the event)*
Is the outcome/tool validated?
Were multiple analyses conducted? (y/n)
Methods of analyses used
- Univariable analyses only
- Univariable and multivariable analyses used
- Interrupted time series analysis
- Survival analysis
- Regression analysis

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(specify type (e.g. linear, logistic, multinomial, cox proportional hazard) and statistic used (e.g. odds ratio, hazard ratio, incidence rate ratio, risk ratio)
- Tests of difference (e.g. t-tests, ANOVA, chi-square)
- Regression analyses
- Time-to-event *(If time-to-event, was Kaplan-Meier curve provided?)*
- Other (please state)
Were subgroup analyses performed? If yes, give details (e.g. analysis stratified by gender, age, or method)
Confounding
Was information gathered on potential confounders?
What method(s) were used to assess and control for confounding?
- Instrumental variable analysis
- Propensity scoring
- Interaction terms
- Multivariable analyses
- Stratification
- Other
Was repetition examined?
Type of repetition
- Person-based
- Presentation-based
- Next act repetition
- Cumulative repetition
- Time to next act/period of repetition
- Frequency of repetition
Repetition examined, details
Were rates used?
- Person-based
- Presentation-based
- What denominator was used
Rates used, details