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Enhanced cognitive behavioural therapy for self-harm in comorbid physical and mental health conditions: a pragmatic randomised controlled trial

Submission date
02/08/2024

Recruitment status
Recruiting

Registration date
21/08/2024

Overall study status
Ongoing

Last Edited
10/03/2025

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Self-harm and suicide represent significant public health concerns in contemporary society. The presence of co-existing physical and mental health issues (comorbid), coupled with neurobiological factors, exacerbates mental health challenges and coping mechanisms, increasing the likelihood of self-harm and suicidal behaviors.
Although research studies have reported findings related to individuals with comorbid conditions, there is currently no research available on the effectiveness of interventions like Cognitive Behavioural Therapy (CBT) specifically tailored for comorbid populations at risk of self-harm and suicide. This study aims to address this by evaluating the effectiveness of CBT in addressing the unique needs of individuals experiencing comorbid physical and mental health conditions, with a focus on preventing and treating self-harm and suicide risk.

Who can participate?
Adults aged over 18 years with chronic physical illness(es) requiring the services of secondary /tertiary care, specifically, cancer or asthma or Chronic Obstructive Pulmonary Disease (COPD) or any type of chronic pain (including fibromyalgia, trauma, or osteoarthritis) persisting over 3 months, and a recent history (within the past 3 months) or risk of self-harm or suicidal behaviors (ideation and act), with comorbid mental health symptom(s) such as anxiety, mild or moderate depressive symptoms, or distress.

What does the study involve?
This study encompasses two primary components. Firstly, it involves administering a 15-week enhanced cognitive behavioral therapy (CBT) intervention along with standard care (treatment as usual) and assessing its impact on psychological factors and biological markers compared to individuals receiving treatment as usual only. Secondly, the study includes the collection of biological samples (blood and saliva) to investigate the intervention's effects on specific biological markers.
In Ireland, the standard care provided for individuals at risk of suicide and self-harm can vary,

although the National Clinical Program has been established to guide healthcare professionals looking after the patients. Typically, individuals may consult their General Practitioners (GPs) or present to Emergency Departments (EDs), where they undergo a comprehensive biopsychosocial assessment followed by appropriate medical care, which may involve pharmacological, psychosocial interventions, or a combination of both.

What are the possible benefits and risks of participating?
The project holds potential benefits for both participants and society at large. The treatment protocol implemented in this study is based on a firm evidence base of Cognitive Behavioural Therapy (CBT) which has been considered as a part of first line of treatment for many mental health conditions. Participants enrolled in this trial will have access to an enhanced form of CBT specifically designed to address self-harming behaviors within the context of co-occurring or comorbid mental and physical health conditions. This tailored intervention aims to provide participants with effective coping strategies, problem-solving skills, and improved self-awareness, ultimately empowering them to manage their conditions more effectively. The study objectives align with international and domestic policy guidelines such as WHO's LIVE LIFE: an implementation guide for suicide prevention in countries and Ireland's connecting for life (CfL). CfL goal 4: better access to supports and goal 7: better data and research are key elements of this project adding to the complementarity of aims. By evaluating the efficacy of this enhanced CBT approach through a pragmatic Randomised Controlled Trial (PrRCT), the project aims to contribute valuable evidence to inform routine clinical practice and policy decisions. Positive outcomes from this trial are likely to contribute to more targeted and accessible interventions for individuals at risk of self-harm and suicide.
One potential risk is related to the sensitive nature of the population, which focuses on self-harm and suicidal behaviors. Engaging in discussions or interventions related to self-harm may trigger emotional distress in participants. To minimise this risk, all participants will undergo screening and assessment by qualified mental health professionals before enrollment, in accordance with previous similar research studies conducted by this research team involving specially trained researchers. The eligibility criteria of the study have been carefully drafted to exclude participants who are living with severe mental health conditions or have immediate healthcare needs due to self-harm/suicidal behaviours. In the event of any adverse reaction or concerns, a safety plan has been put in place as well. The researchers anticipate some risk associated with blood sample collection however it is expected to be minimal primarily associated with the use of a needle to access a large vein in any suitable region in the participant' s arm. Potential risks include bruising at the puncture site, inflammation of the vein, and the rare possibility of infection. To mitigate these risks, clinical standard operating procedures, highlighting correct methods surrounding bio-sampling and precautions will be implemented throughout the blood and saliva collection process. The blood sampling will be conducted by researchers trained in phlebotomy. The researchers will adhere to strict hygiene protocols to minimise the risk of infection. Another risk pertains to the potential for confidentiality breaches, given the personal and sensitive nature of the information shared during therapy sessions. To mitigate this risk, a data management protocol will be implemented, including secure data storage and limited access to participant information by authorised personnel only. Furthermore, participation in a randomised controlled trial may introduce uncertainty regarding treatment allocation and expectations. To address this, participants will receive detailed information about the study design, procedures, and potential outcomes during the informed consent process. They will have the opportunity to ask questions and clarify any concerns before agreeing to participate. Randomisation and allocation will be undertaken using university-licensed software (Castor EDC) to exclude any human intervention in assigning groups.

Where is the study run from?
This study is a collaboration between the School of Public Health, Department of Anatomy and

Neuroscience, University College Cork, and the National Suicide Research Foundation based in Cork, Republic of Ireland.

When is the study starting and how long is it expected to run for?
March 2022 to October 2026

Who is funding the study?
Health Research Board (Ireland)

Who is the main contact?
1. Ella Arensman, ella.arensman@ucc.ie
2. Almas Khan, almaskhan@ucc.ie, enhancedcbtstudy@ucc.ie

Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Study number 24066

Study information

Scientific Title
Enhanced cognitive behavioural therapy for self-harm among people with comorbid mental and physical health conditions: a pragmatic randomised controlled trial

Study objectives
1. In adults living with comorbid physical and mental health conditions, does an enhanced cognitive behavioural therapy reduce suicide and self-harm behaviors (ideation and acts) compared to treatment as usual (TaU)?
2. Does enhanced cognitive behavioural therapy have an influence on psychological measures and biological markers among people living with physical and mental health comorbidities?

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 04/03/2025, Clinical Research Ethics Committee of the Cork Teaching Hospitals (CREC) (Lancaster Hall, 6 Little Hanover Street, Cork, T12 E30P, Ireland; +353 (0)214901901; crec@ucc.ie), ref: Not yet available

Study design
Pragmatic randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital, Other

Study type(s)
Prevention, Treatment, Efficacy

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Self-harm and suicidal behaviours (ideation and act) in comorbid physical and mental health conditions

Interventions
Current interventions as of 05/02/2025:

This study encompasses two primary components. Firstly, it involves administering a 15-week enhanced Cognitive Behavioral Therapy (CBT) intervention along with standard care (treatment as usual) and assessing its impact on psychological factors and biological markers compared to individuals receiving treatment as usual only alone. Secondly, the study includes the collection of biological samples (blood and saliva) to investigate the intervention's effects on specific biological markers related to the HPA axis, neural plasticity/neuroplasticity, tryptophan-kynurenine pathway and inflammation.

In Ireland, the standard care provided for individuals at risk of suicide and self-harm can vary, although the National Clinical Program has been established to guide healthcare professionals looking after the patients. Typically, individuals may consult their General Practitioners (GPs) or present to Emergency Departments (EDs), where they undergo a comprehensive biopsychosocial assessment followed by appropriate medical care, which may involve pharmacological, psychosocial interventions, or a combination of both.

Individual-level stratified randomisation (Biological sex, and severity of suicidal ideation)

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Previous interventions:

This study encompasses two primary components. Firstly, it involves administering a 15-week enhanced Cognitive Behavioral Therapy (CBT) intervention along with standard care (treatment as usual) and assessing its impact on psychological factors and biological markers compared to individuals receiving treatment as usual only alone. Secondly, the study includes the collection of biological samples (blood and saliva) to investigate the intervention's effects on specific biological markers related to the HPA axis, neural plasticity/neuroplasticity, tryptophan-kynurenine pathway and inflammation.

In Ireland, the standard care provided for individuals at risk of suicide and self-harm can vary, although the National Clinical Program has been established to guide healthcare professionals looking after the patients. Typically, individuals may consult their General Practitioners (GPs) or present to Emergency Departments (EDs), where they undergo a comprehensive biopsychosocial assessment followed by appropriate medical care, which may involve pharmacological, psychosocial interventions, or a combination of both.

Individual-level stratified randomisation (age, sex, and physical condition)

Intervention Type
Behavioural

Primary outcome measure

Current primary outcome measure as of 21/01/2025:

1. Repetition and severity of self-harm (thoughts and acts) measured using Deliberate Self-harm Inventory (DSHI) at baseline, post-intervention (15-16 weeks after baseline as 1st follow-up) and 3 months after first follow-up (10-12 weeks post first follow-up)
2. Suicidal behaviours (thoughts and acts) measured using the Suicide Cognition Scale-revised (SCS-R), Beck scale for suicidal ideation (BSSI) at baseline, post-intervention (15-16 weeks after baseline as 1st follow-up) and 3 months after first follow-up (10-12 weeks post first follow-up)

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Previous primary outcome measure:

1. Repetition and severity of self-harm (thoughts and acts) measured using Deliberate Self-harm Inventory (DSHI) at baseline, post-intervention (15-16 weeks after baseline as 1st follow-up) and 3 months after first follow-up (10-12 weeks post first follow-up)
2. Suicidal behaviours (thoughts and acts) measured using the Suicide Cognition Scale-revised (SCS-R), Beck scale for suicidal ideation (BSSI) or the modified scale for suicidal ideation (MSSI) at baseline, post-intervention (15-16 weeks after baseline as 1st follow-up) and 3 months after first follow-up (10-12 weeks post first follow-up)

Secondary outcome measures
1. Severity of depression and anxiety measured using the Patient Health Questionnaire Anxiety and Depression Scale (PHQ-ADS) at baseline, post-intervention (15-16 weeks after baseline as 1st follow-up) and 3 months after first follow-up (10-12 weeks post first follow-up)
2. Coping measured using Brief-COPE at baseline, post-intervention (15-16 weeks after baseline as 1st follow-up) and 3 months after first follow-up (10-12 weeks post first follow-up)
3. Hopelessness measured using the Beck hopelessness scale at baseline, post-intervention (15-16 weeks after baseline as 1st follow-up) and 3 months after first follow-up (10-12 weeks post first follow-up)
4. Burden of comorbid conditions measured using PROMIS-29 2.0 at baseline, post-intervention (15-16 weeks after baseline as 1st follow-up) and 3 months after first follow-up (10-12 weeks post first follow-up)
5. Quality of life and mental wellbeing measured using WHO-5 at baseline, post-intervention (15-16 weeks after baseline as 1st follow-up) and 3 months after first follow-up (10-12 weeks post first follow-up)
6. Biological markers such as hypothalamic pituitary adrenal (HPA)-axis functioning (cortisol), inflammation (C-reactive protein, IL-6, TNF-alpha), tryptophan-kynurenine pathway (tryptophan, kynurenine, kynurenic acid), neuroplasticity (Brain-Derived Neurotrophic Factor [BDNF]) measured using blood and salivary samples at baseline, post-intervention (15-16 weeks after baseline as 1st follow-up) and 3 months after first follow-up (10-12 weeks post first follow-up).

Overall study start date
01/03/2022

Completion date
01/10/2026

Eligibility

Key inclusion criteria

1. Adults over 18 years
2. Presence of a chronic physical illness(es) requiring the services of secondary/ tertiary care, specifically, cancer or asthma or Chronic Obstructive Pulmonary Disease (COPD) or any type of chronic pain (including fibromyalgia, trauma, or osteoarthritis) persisting over 3 months or defined as per ICD-11
3. A recent history (within the past 3 months) or risk of self-harm or suicidal behaviors (ideation and act)
4. Presence of comorbid mental health symptom(s) such as anxiety, mild-moderate depressive symptoms, or distress

Participant type(s)
Patient, Service user

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
180

Key exclusion criteria
1. Below the age of 18 years
2. Not requiring or undergoing secondary treatment
3. Not living with a chronic physical illness including non-melanoma skin cancer
4. Exhibiting high/severe risk of suicidal or self-harm behaviours, where the treating consultant doesn't recommend participation in the study
5. Diagnosed with severe or enduring mental disorders like severe depression or anxiety (score of 9 or more on PHQ-4 screening test), schizophrenia, bipolar affective disorders, personality disorders
6. Significant cognitive impairment
7. Requiring intensive in-patient care due to their medical illness

Date of first enrolment
20/03/2025

Date of final enrolment
30/07/2026

Locations

Countries of recruitment
Ireland

Study participating centre

School of Public Health and National Suicide Research Foundation
Western Gateway Building
Room 4.28
University College Cork
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Study participating centre
Department of Anatomy and Neuroscience
Western Gateway Building
Western Road
Cork
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T12XF62

Study participating centre
Cork University Hospital
Wilton
Cork
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T12 EC8P

Study participating centre
Mercy University Hospital (MUH)
Grenville Pl
Cork
Ireland
T12 WE28

Study participating centre
South Infirmary Victoria University Hospital
Old Blackrock Road
Ballintemple
Cork
Ireland
T12 X23H

Study participating centre
St Mary's Health campus
Gurranabraher Rd

Gurranabraher
Cork
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P31 XN96

Study participating centre
National Suicide Research Foundation
4, Western Gateway Building
Western Rd
Mardyke
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T12 XF62

Study participating centre
St Catherine's Convent
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Sponsor information

Organisation
University College Cork

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Sponsor type
University/education

Website
https://www.ucc.ie/en/

ROR
https://ror.org/03265fv13

Funder(s)

Funder type
Government

Funder Name
Health Research Board

Alternative Name(s)
Health Research Board, Ireland, An Bord Taighde Sláinte, HRB

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Ireland

Results and Publications

Publication and dissemination plan
After conducting the trial, our primary goal is to efficiently distribute the findings to a diverse array of stakeholders and the wider academic community. To achieve this, the researchers plan to publish the results in respected peer-reviewed journals relevant to the field. Furthermore, they intend to utilise prominent academic platforms such as ResearchGate to connect with scholars, researchers, and practitioners who can both benefit from and contribute to the insights derived from the review.

In addition to traditional publication routes, we will disseminate the findings through various channels including seminars, webinars, and social media platforms like LinkedIn and X (formerly Twitter). These avenues will enable us to engage with a broad audience and foster discussions around the implications of our findings.

Recognising the importance of accessibility, we will explore the creation of visual summaries, such as posters, to effectively communicate the key outcomes of the trial in a format that is easily understood by a wider audience. This approach aims to enhance the reach and impact of our research, ensuring that the insights garnered are accessible and beneficial to as many individuals as possible.

Intention to publish date
01/11/2026

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request and assessment from Prof. Ella Arensman, Principal investigator (ella.arensman@ucc.ie). Informed consent will be obtained. Data will be pseudonymised and patients will be assigned with a unique patient ID.

IPD sharing plan summary

Available on request