Note: Each Ethics Committee or Institutional Review Board will revise and adapt according to their own institution's guidelines.

Consent Form for Participants

Study Title: Enhanced Cognitive Behavioural Therapy for Self-harm among people with Comorbid Mental and Physical Health Conditions: a pragmatic Randomised Controlled Trial.
Version: v1.4, 13/04/2026
Participant study number:
Prof Ella Arensman, School of Public Health, University College Cork.
Email: ella.arensman@ucc.ie

Thank you for agreeing to take part in our project. The purpose of this form is to make sure that you agree to take part in the research and that you know what it involves.

		Signature/Initials
Regarding the overall project:		
	I confirm that I have read and understood the information sheet for the project, I have received a copy and have had the opportunity to ask questions.	
	I understand that my participation is voluntary and that I am free to withdraw at any time, without giving a reason and I understand that opting out will not affect my future medical care.	
	I understand that this study involves me providing biological samples (blood and saliva)	
	I agree to provide the required amount of blood samples (approx. 20 ml per study visit)	
	I agree to provide the required number of salivary samples	
	I understand that the biological samples (blood and saliva) obtained within this project will be stored securely in a pseudonymised manner.	
	I understand that the results of any biological samples will not be shared with me.	

	I give permission for researchers to ask for my current medications/ treatment. I have been assured that information about me will be kept private and confidential.	
	I consent that my participant will involve informing my treating physician/GP about my participation in the study.	
	I have been given a copy of the information leaflet and I will be given a copy of this completed consent form for my records.	
	I consent to take part in this research study having been fully informed of the risks, benefits, and alternatives.	
	I give informed explicit consent to have my data processed as part of this research study.	
	I agree to be contacted by a member of the research team for further questions in relation to the project by the provided contact details.	
	If eligible, I consent to being contacted for participation in future research studies related to this project.	
Regarding the data management and security:		
	I understand that the data obtained within this project will be stored securely in a pseudonymised manner.	
	I understand that my pseudonymised data may be presented in publications, reports, and meetings.	
	I understand that my data will be kept for 10 years according to the UCC Code of Research Conduct	
	I understand that confidentiality of records concerning my involvement in this project will be maintained in an appropriate manner. When required by law, the records may be reviewed by government agencies/sponsors of the research/University College Cork and the Clinical Research Ethics Committee of the Cork Teaching Hospital	
	The sponsors and investigators have such insurance as is required by law in the event of injury as a direct result of my participation in the study.	
	If I have further questions concerning the study, I can contact the Chief Investigator: Ella Arensman	

	The study has been approved by the Clinical Research Ethics Committee of the Cork Teaching Hospitals (CREC) and if I have further queries concerning my rights in connection with the research, I can contact the CREC at Lancaster Hall, 6 Little Hanover Street, Cork by email at crec@ucc.ie.	

I, the undersigned, hereby consent to participate in the above-described project: _____ **Name of the participant: _____** **Date: _____** **Email address: _____** **Phone number: _____**	
Witness Name, signature and date (if applicable)	
Legally Appropriate Representative name, signature and date (if applicable)	
Investigator Signature and date:	
I have been given a copy of this leaflet, please tick:	☐ Yes ☐ No
Patient's GP's name (to inform about participation once consent is signed)	