A single-blind, parallel-group randomised trial of a Technology-assisted and remotely delivered Cognitive Behavioural Therapy intervention (Tech-CBT) versus usual care to reduce anxiety in people with mild cognitive impairment and dementia:

Statistical Analysis Plan

Version 1.0, Dated 29 January 2026

The preparation of this document has been led by the trial statistician, who will remain blinded until this document has been agreed and uploaded to: https://clinicaltrials.gov/study/NCT05528302.

This document has been approved by the following:

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Introduction

The study protocol has been published in *Trials*: https://doi.org/10.1186/s13063-023-07381-2

This document describes how the quantitative data (with the exception of the health economic data) will be reported and analysed in the main results publication.

Reporting and analysis of outcomes

In the protocol (and on the trial registry), one primary outcome and 11 secondary outcomes were listed. Some detail on the outcome measures is provided in the Table below. The primary timepoint is T2 (Week 8).

Table. Outcomes

		Range	Baseline	Post-baseline		
			T1	T2 (Week 8)	T3 (Week 20)	T4 (Week 32)
	Primary Outcome					
	Rating Anxiety in Dementia (RAID)	0 – 54	X	X	X	X
	Secondary Outcomes					
	-All participants living with MCI/dementia-					
1	Quality of life in Alzheimer's disease (QoL-AD)	13 – 52	X	X	X	X
2	Geriatric Anxiety Inventory (GAI)	0 – 20	X	X	X	X
3	Penn State Worry Questionnaire (PSWQ-A)	8 – 40	X	X	X	X
4	Perceived Stress Scale (PSS-14)	0 – 56	X	X	X	X
5	Geriatric Depression Scale (GDS-15)	0 – 15	X	X	X	X
	-People living with PD and MCI/dementia-					
6	Parkinson's Anxiety Scale (PAS)	0 – 48	X	X		
7	Parkinson's disease Specific Anxiety Inventory (PDSAI)	0 – 40	X	X		
8	Patient Reported Outcomes in Parkinson's Disease (PRO-PD)	0 – 3500	X	X	X	X
	-Support persons-					
9	Zarit Burden Inventory (ZBI)	0 – 88	X	X	X	X
10	Assessment of quality of life (AQoL-6D)	20 – 99	X	X	X	X
11	Depression, Anxiety and Stress Scale (DASS-21)	0 – 126	X	X		

Note. Worst score coloured in red.

Analysis of primary outcome and secondary outcomes 1-5 and 9-10

We will use a linear mixed model to estimate adjusted between-group differences in change from baseline at the post-baseline timepoints. The model will include fixed effects for the outcome at baseline, gender of participant living with MCI/dementia, randomisation group, post-baseline timepoint (i.e. T2, T3 or T4) and interactions between group and timepoint. Participant will be a random effect. The model will be fit via restricted maximum likelihood (REML) and the Kenward-Roger method used for computing degrees of freedom of a t-distribution.

i.e.

on a dataset that looks like this:

record_id	randgroup	time	outcome	baseline	change_outcome
1001	2	2	9	28	-19
1001	2	3	5	28	-23
1001	2	4	14	28	-14

the following Stata syntax will be used to estimate the between-group difference (intervention(1) – control(2)) in change from baseline

at T2: . mixed change_outcome baseline ib2.randgroup##ib2.time i.gender if time>1 || record_id:, reml dfmethod(kroger)

at T3: . mixed change_outcome baseline ib2.randgroup##ib3.time i.gender if time>1 || record_id:, reml dfmethod(kroger)

at T4: . mixed change_outcome baseline ib2.randgroup##ib4.time i.gender if time>1 || record_id:, reml dfmethod(kroger)

Note, the above syntax fits the same model (three times). It just expresses the model in different ways, so that the between-group differences at T2, T3 and T4 can be obtained with the Kenward-Roger DF method.

Analysis of secondary outcome 11 (DASS, just assessed at T1 and T2)

We will use an ANCOVA model to estimate the between-group difference in change from baseline at T2. Fixed effects will be randomisation group, gender of the participant living with MCI/dementia and the outcome at baseline.

The following Stata syntax will be used:

```
. regress change_outcome baseline ib2.randgroup i.gender if time==2
```

Analysis of secondary outcomes 6-8

Due to limited post-baseline data*, there will be no analysis of the outcomes for participants living with PD and MCI/dementia.

*At a post-baseline timepoint, no more than n=3 will have data for one of these outcomes.

Presenting data and analyses

We will report the data relating to the outcomes in the tables below,

and produce line graphs showing mean outcome and 95%CI for each group at each timepoint, calculated using syntax like this:

```
. mixed outcome time#randgroup i.gender  || record_id:, reml
. margins time#randgroup
. marginsplot
```

Table 1

Baseline Characteristics, by Randomised Group

Variable	Tech-CBT Group (*n* =)		TAU Group (*n* =)		Test Statistic
	n (%)	Mean (SD)	*n* (%)	Mean (SD)	
Age					
Gender (% female)					
Diagnostic aetiology					
MCI					—
Dementia					—
TICS-M					
IADL					
Participating with support person					
Language other than English					
Living in regional or remote area [a]					
Years of formal education					
Subjective reports of anxiety					
Self-report diagnosis of anxiety disorder					—
Self-report diagnosis of depressive disorder					—

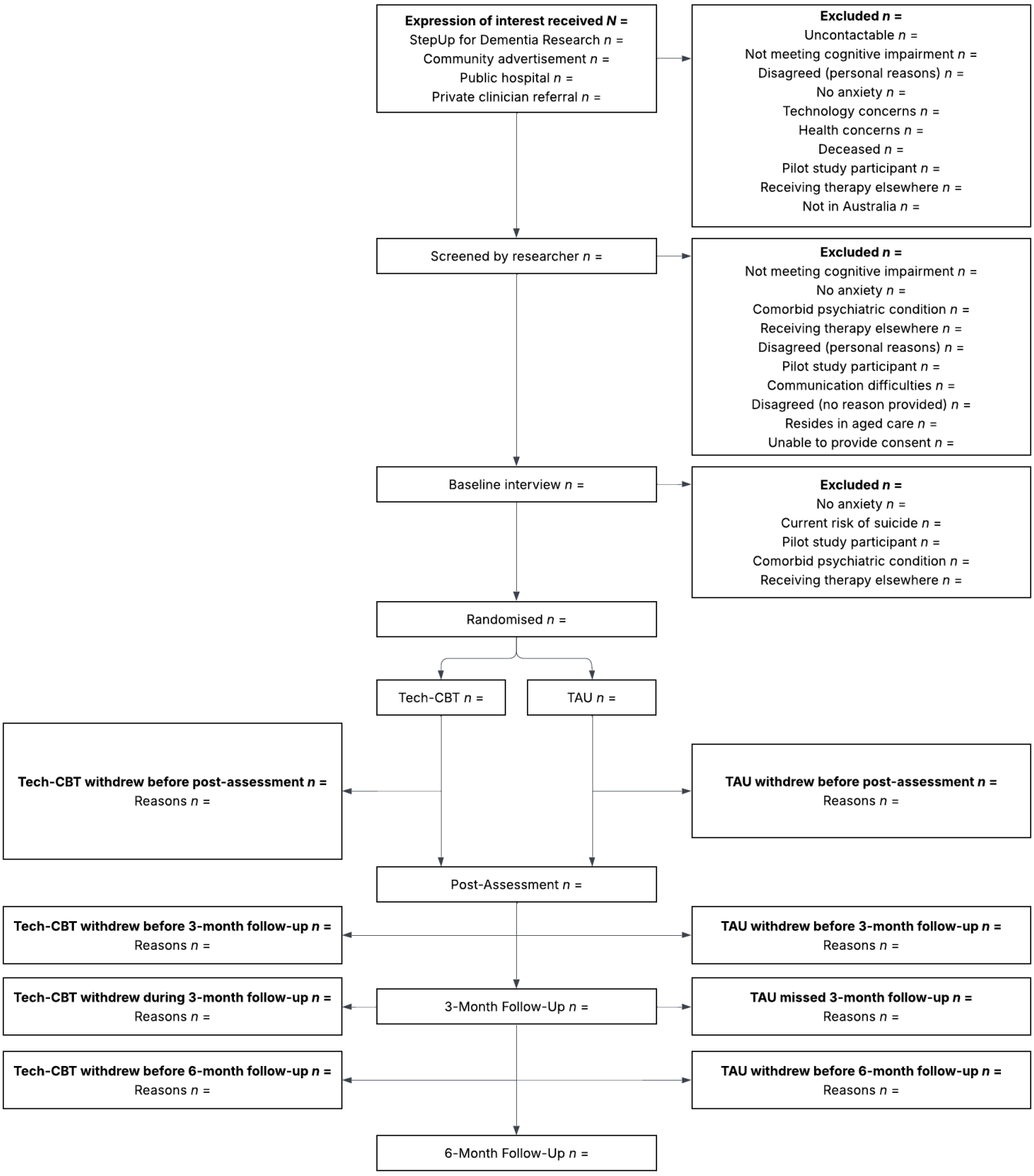
Note. N people living with cognitive impairment = . *n* = 1 support person did not provide baseline responses. TAU = Treatment as usual. SD = Standard deviation. MCI = Mild Cognitive Impairment. TICS-M = Modified Telephone Interview for Cognitive Status. IADL = Lawton Instrumental Activities of Daily Living. Test statistic is *t*(df) for continuous data and $\chi^2(1)$ for categorical data.

[a] Rural or Regional area defined as Modified Monash Model classification 2-7 (2023).

*$p < .05$, **$p < .01$, ***$p < .001$

Figure 1

CONSORT Flowchart of Screened Participants



Note. TAU = Treatment as usual. StepUp for Dementia Research is funded by the Australian Government Department of Health and implemented by a dedicated team at the University of Sydney (Jeon et al., 2021).

Table 2

Outcomes for People Living with Cognitive Impairment and their Support Persons

	Baseline *M*(SD)	Post *M*(SD)	3-Month *M*(SD)	6-Month *M*(SD)	Post adjusted mean difference (95% CI)	3-Month adjusted mean difference (95% CI)	6-Month Adjusted mean difference (95% CI)
Measures for People Living with Cognitive Impairment							
RAID							
Tech-CBT	x.x (x.x)	x.x (x.x)	x.x (x.x)	x.x (x.x)	x.x [x.x, x.x]*	x.x [x.x, x.x]*	x.x [x.x, x.x]*
TAU	x.x (x.x)	x.x (x.x)	x.x (x.x)	x.x (x.x)			
GAI							
Tech-CBT							
TAU							
PSWQ-A							
Tech-CBT							
TAU							
PSS-14							
Tech-CBT							
TAU							
GDS-15							
Tech-CBT							
TAU							
QoL-AD							
Tech-CBT							

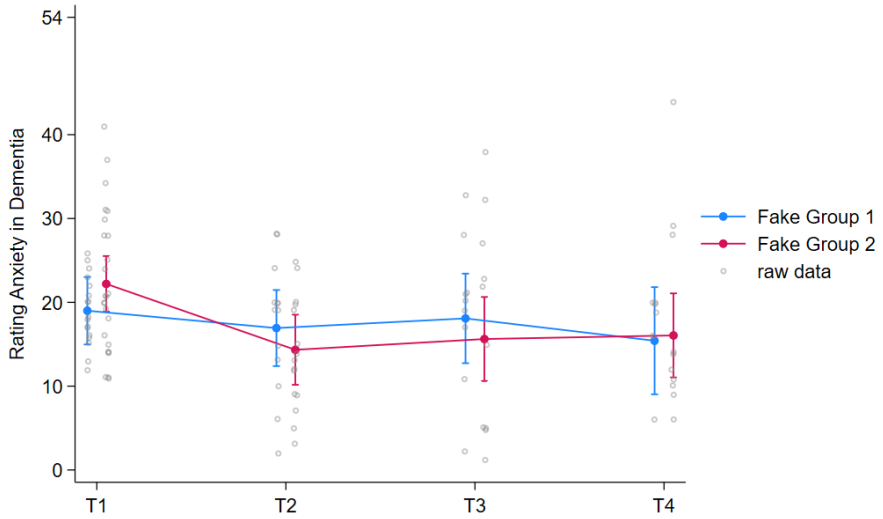
TAU	
Measures for Support Persons	
AQoL	
Tech-CBT	
TAU	
ZBI	
Tech-CBT	
TAU	
DASS-21	
Tech-CBT	
TAU	

Note. M = Mean. SD = Standard deviation. RAID = Rating Anxiety in Dementia. TAU = Treatment as usual. GAI = Geriatric Anxiety Inventory. PSWQ-A = Penn State Worry Questionnaire. GDS-15 = Geriatric Depression Scale. QoL-AD = Quality of Life in Alzheimer's Disease. AQoL = Assessment of Quality of Life. ZBI = Zarit Burden Inventory. DASS-21 = Depression, Anxiety and Stress Scale 21.

*$p < .05$. **$p < .01$. ***$p < .001$.

Figure 2

Rating Anxiety in Dementia Mean Scores at Each Timepoint



Note. For readability, line graphs showing the mean and 95% confidence interval of each outcome will be provided in the supplementary of the article, unless a notable trend emerges that warrants discussion in the main text.

Supplementary Table 1

More information on Outcomes for People Living with Cognitive Impairment and their Support Persons

Outcome	Timepoint	Group	*n*	Mean (SD)	Between-group *t*(df) [a]	*n* change	Mean change (SD)	Adjusted mean difference (95% CI)
Measures for People Living with Cognitive Impairment								
RAID	Baseline	Tech-CBT	X	X	X*			
		TAU	X	X				
	Post	Tech-CBT	X	X		X	X	X [X , X]*
		TAU	X	X		X	X	
	3-Month	Tech-CBT	X	X		X	X	X [X , X]*
		TAU	X	X		X	X	
	6-Month	Tech-CBT	X	X		X	X	X [X , X]*
		TAU	X	X		X	X	
GAI	Baseline	Tech-CBT						
		TAU						
	Post	Tech-CBT						
		TAU						
	3-Month	Tech-CBT						
		TAU						
	6-Month	Tech-CBT						
		TAU						
PSWQ-A	Baseline	Tech-CBT						
		TAU						

	Post	Tech-CBT
		TAU
	3-Month	Tech-CBT
		TAU
	6-Month	Tech-CBT
		TAU
PSS-14	Baseline	Tech-CBT
		TAU
	Post	Tech-CBT
		TAU
	3-Month	Tech-CBT
		TAU
	6-Month	Tech-CBT
		TAU
GDS-15	Baseline	Tech-CBT
		TAU
	Post	Tech-CBT
		TAU
	3-Month	Tech-CBT
		TAU
	6-Month	Tech-CBT
		TAU
QoL-AD	Baseline	Tech-CBT
		TAU

	Post	Tech-CBT
		TAU
	3-Month	Tech-CBT
		TAU
	6-Month	Tech-CBT
		TAU
Measures for Support Persons		
DASS-21	Baseline	Tech-CBT
		TAU
	Post	Tech-CBT
		TAU
ZBI	Baseline	Tech-CBT
		TAU
	Post	Tech-CBT
		TAU
	3-Month	Tech-CBT
		TAU
	6-Month	Tech-CBT
		TAU
AQoL	Baseline	Tech-CBT
		TAU
	Post	Tech-CBT
		TAU
	3-Month	Tech-CBT

	TAU	
6-Month	Tech-CBT	
	TAU	

Note. SD = Standard deviation. RAID = Rating Anxiety in Dementia. TAU = Treatment as usual. GAI = Geriatric Anxiety Inventory. PSQQ-A = Penn State Worry Questionnaire. GDS-15 = Geriatric Depression Scale. QoL-AD = Quality of Life in Alzheimer's Disease. AQoL = Assessment of Quality of Life. ZBI = Zarit Burden Inventory. DASS-21 = Depression, Anxiety and Stress Scale 21.

[a] Between-group *t*(df) refers to differences between groups at baseline.

Supplementary Table 3

Differences Between Completers and Non-Completers

Characteristic	Completed RAID post-assessment (*n* =)	Did not complete RAID post-assessment (*n* =)	Test Statistic
Sociodemographic Characteristics			
Age			
Gender (% female)			
Diagnostic aetiology			
MCI			—
Dementia			—
Participating with support person			
Language other than English			
Living in regional or remote area			
Years of formal education			
Subjective reports of anxiety			
Self-report diagnosis of anxiety disorder			—
Self-report diagnosis of depressive disorder			—
Baseline Measures			
RAID			
GAI			
PSWQ-A			
PSS-14			
GDS-15			

TICS-M

IADL

QoL-AD

ZBI

AQoL

DASS-21

Missing data

When a whole questionnaire/scale is missing at T1/T2/T3/T4, we will NOT impute a total/score.

Therefore, in order to include a person's data in an analysis of an outcome, we need the person to have i) the outcome at baseline and ii) at least one outcome post-baseline.

When just one item is missing from a questionnaire/scale, a total will be calculated by utilising their item score from the most recent administration.