

REGAIN Randomisation

Randomisation will happen automatically after the baseline questionnaire is completed if the pt meets the following:

- **REGAIN ID**

Patient Requirements

- **Does the patient meet all of the eligibility criteria?**

Must be Yes

Pull through answer and completion date from Eligibility Form

- **Has the patient completed a consent form meeting all consent requirements?**

Must be Yes- system will check for presence of a completed consent form that meets all the mandatory consent requirements.

Pull through Version number and date of consent form and completion date from the consent form

- **Has the patient completed the baseline questionnaire?**

Must be Yes- system will check for a completed baseline questionnaire

Pull through Version number and date and completion date from the baseline questionnaire

Stratification

- **Age**

Pull through from DOB on eligibility form.

We base grouping on a median age of 65 years old.

Less than 65

Equal to and above 65

- **Is Case Level Mental Health symptoms present?**

Yes/No field based on answers to certain measures in the Baseline Questionnaire.

One or more disorder hitting threshold will count as a Yes for this field.

Measures from Baseline Q =

PTSD score: ≥ 11 is classified as case level. Scoring is based on 6 IES-r measures only, not the full 22 questions.

HADS score: ≥ 11 is case level

- **Level of Hospital Care**

Two options: Intensive Care Unit/High Dependency Unit; Ward

Data from the Level of Hospital Care question in the eligibility form will be pulled through for this variable.

Where an answer of 'I don't know' or 'I did not stay in ICU/HDU' are given to this question, the system should interpret this as the answer 'Ward'.

- **Allocation**

Online Exercise Rehabilitation and Psychological Support Programme (Intervention) or

Online Exercise Advice and Support (Control)

Ratio is 1:1.03, control:intervention

Automatic emails

- **Participant email to go out upon randomisation to intervention and control (English speaking pts only)**

Dear REGAIN participant,

You have successfully been randomised into the REGAIN study.

Your REGAIN participant number is: REGXXX

An exercise specialist will be in touch soon to let you know which treatment group you have been placed into and to book your first study appointment.

Thank you for taking part in the REGAIN Study!

- **Practitioner allocation email to go out upon randomisation to intervention (English speaking pts only)**

The practitioners will be the same for all pts regardless of treating hospital because all intervention and control are run out of Atrium Health. So the database just needs updating with who should get these emails of the Atrium Health staff.

Dear REGAIN Practitioner,

REGAIN participant [REGAIN ID] has been randomised to the Arm A: Intervention Online Exercise Rehabilitation and Psychological Support Programme.

Please contact the participant directly to book in their one hour individual assessment.

If the participant has met the threshold for case level mental health symptoms as from their baseline questionnaire, the details of this will be displayed below. Please discuss with the participant, advise them to see their GP and inform them that the REGAIN team will notify their GP of this via letter. If the participant does not attend the individual assessment, please inform the REGAIN team who will send a letter to the participant advising them to see their GP.

Pull through any case level mental health disorders from the baseline questionnaire/stratification variable and display them here.

Many thanks from the REGAIN Team

- **Practitioner allocation email to go out upon randomisation to control (English speaking pts only)**

Dear REGAIN Practitioner,

REGAIN participant [REGAIN ID] has been randomised to Arm B: Control Online Exercise Advice and Support.

Please contact the participant directly to book in their 30 minute one to one consultation.

If the participant has met the threshold for case level mental health symptoms as from their baseline questionnaire the details of this will be displayed below. Please discuss with the participant, advise them to see their GP and inform them that the REGAIN team will notify their GP of this via letter. If the participant does not attend the control consultation, please inform the REGAIN team who will send a letter to the participant advising them to see their GP.

Pull through any case level mental health symptoms from the baseline questionnaire/stratification variable and display them here.

Many thanks from the REGAIN Team

- **CTU allocation email to go out upon randomisation to REGAIN resource account (for both English speaking and non-English speaking pts)**

REGAIN ID

Chosen Language

Arm