ReCAPS Feasibility Questionnaire

This questionnaire is intended to give you an idea of what is required for the ReCAPS protocol to run successfully at your site. It is also useful for the Central Research team to get an idea of your interest in the trial, your ability to conduct the trial, and how your site is setup to be involved in the research
It is preferable that the person who is likely to take on the Principal Investigator role at your site, completes this form. Please use the comments section below if required.

Link to online version if preferred: ReCAPS Feasibility Survey

Site Contact Details

Type of Hospital
Public Hospital ☐
Private Hospital ☐

Site Address:

Type of Stroke Service
Acute stroke Unit ☐
Geographically located stroke admissions ☐
Combined acute and rehab stroke service ☐

Principal Contact Person
Name:

Phone:

Email:

Secondary Contact Person (if applicable)
Name:

Phone:

Email:

Type of education or post discharge support available at your site:

1. Clinics with focus on secondary prevention education: ☐
2. Programs with patient access to advice post-discharge: ☐
3. Rehabilitation in the home: ☐
4. Nothing like this available at my site: ☐
5. Other, please describe:

Trial Management

For this trial, it is required that one person takes on the Principal Investigator role at your site. This person will be the Principal contact person for the trial and will be responsible for overseeing the trial, ensuring data is uploaded and managing site trial staff at your site. This person may also be the person most closely involved in the screening and recruitment of new patients, however this responsibility can also be delegated to another member of the team. Prior experience of the PI role is not essential but being able to dedicate time to the trial is required.

	Yes	No
• Is there a staff member willing and able to take on the Principal Investigator role? Name: Email:	☐	☐
• Does the investigator work within a dedicated stroke care unit/ward?	☐	☐

• Does the Principal Investigator at the site have time to oversee and manage the trial at the site?	☐ ☐
• Does the Principal Investigator have other clinical trials that they are involved in?	☐ ☐
Number of other studies:	

Clinical Trial Experience

Experience in the running of clinical trials is not required, just a healthy interest in research and a willingness to undertake relevant training as required.

	Yes	No
• Has the Principal Investigator had previous experience in running clinical trials?	☐	☐

Trial staffing, roles and responsibilities

For this trial it is essential that there is support by the head of department, medical staff, nursing staff and other allied health stroke unit personnel as they may be invited to be involved in the trial.
The Principal Investigator is involved in the overall running of the trial at the site and may be directly involved in the screening and recruitment of patients, in addition to being involved in the implementation of the protocol. These tasks may also be delegated to other team members.
Stroke Unit nurses, allied health (physiotherapists, speech and occupational therapists) and stroke trial nurses will work together as a team to implement the self-management support package to the participants before discharge.
Medical personnel in the stroke unit need to be supportive of the project to ensure that the protocol can be implemented. They would also be required to assist in making medical decisions regarding the inclusion of patients, baseline stroke assessments and reporting of adverse events/serious adverse events as required.

	Yes	No
• Does the Principal Investigator have the support of the nursing **and** allied health departments?	☐	☐
• Does the Principal Investigator have the ability to delegate some responsibilities of the trial to ensure that the requirements of the protocol are met?	☐	☐
• Does the Principal Investigator have the support of departmental medical staff?	☐	☐
• Is there a medical staff member who is willing and able to commit to the medical aspects of the study at your site?	☐	☐
Name: Email:		
• Is there departmental support for this trial on the stroke care unit/ward?	☐	☐
• Are there nursing staff that are able and willing to commit to the study?	☐	☐
• Are other allied health members of the stroke unit supportive of the trial?	☐	☐
• Have team members completed training in administering the Modified Rankin Scale?	☐	☐

Funding

A per patient payment will be made and paid into a special purpose fund for the trial at your site. Payments will be made for the screening, recruitment and baseline assessments.

	Yes	No
• Will you be able to set up a special purpose fund for the transfer of these funds?	☐	☐
• Can the funds be made available to involved staff for professional development activities such as conference attendances?	☐	☐

Trial Population

Prior to committing to this study, it is important that your stroke unit are likely to be able to enrol approximately 60-80 patients per year. We are interested in how many stroke patients you would see per year that would be potentially eligible for the trial.

Inclusion	**Exclusion**
• Aged ≥ 18 years; • Confirmed diagnosis of acute stroke; • Participants discharged directly to a home setting from a stroke unit and within 10 days of admission; • Have access to the internet; • Self-identify as users of SMS/email technology; • Ability to communicate in English; • Have a baseline Modified Rankin Score of 0-4 (i.e. may require some assistance but not constant care); • Ability to provide own consent	• Participants referred to in-hospital rehabilitation; • Have significant language impairments that impact ability to communicate wishes and goals; • Poor prognosis (unlikely to survive to 90 days).

	Yes	No
• Are stroke audits completed for stroke patients at your site?	☐	☐
• If so, when was the last audit completed? (Date)		
• Approximate number of stroke patients admitted to the hospital in the last year:		
• Number of patients who would be deemed eligible for this trial based on inclusion criteria above in the last year?		

Protocol

A protocol synopsis has been provided for your information with this questionnaire. The full protocol will be provided to your site once your interest and capability of running the trial is established. A Clinical Trial Research Agreement will need to be signed following site governance approval.
Participants involved in the trial will be randomised to receive one of two self-management support package that comprise of: a) structured and comprehensive patient-centred goal setting that is initiated in the hospital and reviewed with a trained clinical researcher via phone within 7-14 days of discharge; and b) electronic personalised and tailored support messages aligned to the patient nominated goals provided for 12 weeks via SMS or email.
Outcome measures will be collected at 90 days and 12 months post discharge by Monash university researchers.

Trial timelines/recruitment requirements

The trial will be recruiting patients for approximately 4 years. Each site is asked to recruit at least 60 patients. Each patient recruited is involved in follow up, for 12 months. If trial staff leave your hospital, it would be required that replacements are trained to ensure the continuation of the study at the site. The study team would assist in this training where required.

	Yes	No
• Is the Principal Investigator able to commit to the length of the trial?	☐	☐
• Are there additional staff who would be willing and able to take on the Principal Investigator role in the case that proposed staff leave during the trial?	☐	☐
	☐	☐

• Are there sufficient patients through the hospital to ensure that recruitment requirements are met in the given timeline?	

Commitments to other studies

If your hospital is committed to other stroke studies, it may mean that there is competition for patients to be enrolled in these studies. Sometimes, studies with similar inclusion criteria will mean the ability to recruit for this trial is lessened.

	Yes	No
• Is the stroke unit committed to any competing studies?	☐	☐
If yes, how many:		
• If so, will this impact on the recruitment for this study (e.g. – Would pharmaceutical trials at your centre have priority over non-drug studies)?	☐	☐
Please list any competing studies at your site:		

Informed consent procedure

It is required that written informed consent is provided by the participant prior to their involvement in the trial. It is a requirement that the trial is explained to the patient by an appropriately trained staff member, and that the participant is given the ethics approved version of the patient information sheet and consent. Participants must have the opportunity to ask questions and have the ability to withdraw from the trial at any time.

	Yes	No
• Do you see that there will be any issues relating to informed consent at your hospital?	☐	☐
If yes, please make comment:		

Facilities adequate for protocol requirements

Stroke patients will need to be recruited within a 10 day window of their admission. If they are discharged home early, they can be brought back into a clinic/ward to complete the baseline assessment as long as it is completed within 7 days of discharge. Some hospitals have a discharge program where patients receive home-based community rehabilitation. This does not exclude them from participating in ReCAPS. Data will be entered into REDCap (an online web based secure data base) at the time of the assessment. For this reason, regular access to the internet is required. Trial worksheets, tools and manuals will be provided by the trial.

	Yes	No
• What is the average length of stay for stroke patients at your site? days		
• Does your hospital have an early discharge program with home-based rehabilitation?	☐	☐
• Where do patients generally receive step down care after their acute admission?		
• Will staff have access to regular internet for the purpose of this trial?	☐	☐

Storage facilities adequate for trial equipment/documents

Any trial equipment or documentation is to be kept confidential at all times, accessed by trial staff only as required. At the end of the trial, source documents (paper and electronic) pertaining to the patients involved need to be kept for 7 to 15 years, depending on the regulatory requirements for your location.

	Yes	No
• Are there locked facilities available at the site for the storage of trial documents and equipment?	☐	☐

• Where is it located and who has access to the area? • Do medical records have a system for recording patients that are involved in a trial?	☐ ☐

Ethics Committee Requirements

Prior to conducting the study at your hospital, it is essential that your hospital ethics committee have reviewed and approved the study.
The Principal Investigator at each site will be responsible for obtaining ethics approval to conduct the study at their site and updating the committee on a regular basis (usually annually). The committee will also need to be informed of Serious Adverse Events (SAEs) and any changes in the study protocol or trial staffing.

Good Clinical Practice Requirements

This is an international ethical and scientific quality standard, for the design, conduct, recording and reporting of clinical trials involving human subjects. Compliance with ICH GCP guidelines assure that the rights, safety and wellbeing of trial subjects are protected and that trial results are credible. Trial management can assist with this training as required.

	Yes	No
• Does the Principal Investigator have current ICH GCP certification?	☐	☐

Monitoring requirements/frequency

To comply with the requirements above, routine monitoring of the study sites involved in the trial will take place. In addition, remote monitoring will occur through the REDCap system. A member of the study team will visit occasionally and look over the documentation and processes at your site to ensure compliance.

	Yes	No
• Are your medical notes paper or electronic?		
• Are there any particular access requirements (such as permission/release for the monitor to access electronic medical records)?	☐	☐
• If yes, please briefly describe requirements:		
• Will site staff be available to spend some time with the monitor during the visit?	☐	☐

Access to source data

Source data is the information that is documented at your site that reflects the patient's care and treatment. It is also possible that records may be needed for audit or review from a representative of the Central Research team, local ethics committees or other regulatory authorities.

	Yes	No
• Are there any anticipated problems pertaining to access of medical records for trial patients?	☐	☐
• Will medical records be available for monitoring visits to the site?	☐	☐
• Will the medical records be available to the Assessor?	☐	☐

Reporting of Adverse events

Adverse events that occur in patients involved in the trial will be documented. An adverse event is any untoward medical experience in any patient involved in the study which is not necessarily caused by the study treatment. Events that are serious by definition, will be reported as soon as possible to the study team. Events that are serious, unexpected, and possibly related to study treatment need to be reported to the sponsor as soon as possible.

	Yes	No
• Do you foresee any issues relating to the documentation and reporting of adverse events?	☐	☐

Do you consider your site to be able to successfully conduct this trial?

Yes ☐ No ☐ Reporter's Name: Date:

Thank you for taking the time to complete this questionnaire. If you have any questions at all, please contact Jan Cameron jan.cameron@monash.edu A member of the Study team will be in touch with you soon.

Schedule of Events

Assessment	Baseline	Post Discharge	Treatment period	3 month follow Up	12 month health economic evaluation
Timepoint	Within 24 hours of planned discharge	7-14 days post discharge (+/- 3 days)	12 weeks	Week 13 post randomisation* +/- 7 days	Week 52 post randomisation* +/- 7 days
Screening/Eligibility	X[1]				
Consent	X[1]				
Goal setting initiated using the ReCAPS structured methods	X[1]				
Goals clarified to ensure they meet SMART criteria		X[2]			
Quality (GEM) scoring on goals			X[3]		
Goal Attainment Scale (GAS)			X[3]	X[5]	
Baseline information (demographics, past medical history, lifestyle, use of electronic devices/apps, self-management survey)	X[1]				
Healthcare Resource Utilisation Questionnaire	X[1]			X[5]	X[7]
Health Education Impact Questionnaire (HeiQ)	X[1]			X[5]	
Stroke Self-Efficacy Questionnaire (SSEQ)	X[1]			X[5]	
Hospital Anxiety Depression Scale (HADS)	X[1]			X[5]	
EuroQoL-5D -3L	X[1]			X[5]	X[7]
mRS	X[1]			X[5]	
PREPARED Survey		X[2]			

Schedule of Events (continued)

Assessment	Baseline	Post Discharge	Treatment period	3 month follow Up	12 month health economic evaluation
Longer-term Unmet Needs (LUNS)		X[2]		X[5]	
Randomisation		X[2]			
Intervention			X[3]		
X2 Electronic reminders for follow up visit			X[4]		
ReCAPS Feedback Survey (control group)				X[6]	
ReCAPS Feedback/acceptability of technology survey (intervention group)				X[6]	
Qualitative interviews/Focus groups				X[6]	

1 – Screening, consent and baseline measures conducted by trained research or stroke unit staff. Patient-centered goal setting, using the ReCAPS structured methods is initiated in the hospital with a clinician.
2- Telephone follow-up 7-14 days post discharge conducted by Monash RA. Goals that were initiated in hospital are clarified with the participant to ensure they meet the SMART requirements for standardised GAS scoring at the 90day outcome assessment. Longer-term Unmet Needs (LUNS) and PREPARED survey administered over the phone. Participant then randomized and masked to group allocation.
3- For participants in the intervention group the RA reviews their goals and schedules the electronic health messages over the 12 week treatment period. Messages are scheduled with a staggered approach according to the priority of the goal. For participants in the control group the RA schedules six welcome and administrative messages with one sent in first week post randomization with details of Stroke Foundation website. SMART goals are quality assessed using GEM criteria by a Monash RA independent of the 7-14 day follow-up. GAS scaling with pre-defined targets are set based on the participant's baseline status (-2 score), and their SMART goal (0 score). The additional GAS scaling categories (-1= slightly worse than expected; -2= no progress made towards achieving goal; +1= somewhat better than expected; +2= much better than expected) are entered into REDCap by a Monash RA prior to the 90 day outcome assessment.
4 – Electronic reminders x 2 for follow up visit (participant preference) one in week 8 post randomisation; and one in week 11 post randomization. Questionnaire pack sent to participants 1 week prior to 13 week scheduled follow-up assessment including HeiQ, SSEQ, mRS, HADS, EQ-5D, GAS, LUNS, Hospital Resource Utilization Survey.
5 – 90 day outcome assessment conducted by Monash RA masked to group allocation and information collected.
6 – Feedback survey performed at the conclusion of the twelve week treatment period for participants and staff.
7 - Questionnaire pack sent to participants 1 week prior to 52 week scheduled outcome assessment including EQ-5D, and Hospital Resource Utilisation Survey. Outcome assessment conducted by Monash RA masked to group allocation and information collected. Hospital readmission, MBS and PBS data obtained from linked AIHW data.