ISRCTN95662526 https://doi.org/10.1186/ISRCTN95662526

The YOU CALL - WE CALL trial: impact of a multimodal support intervention after a "mild" stroke

Submission date 11/07/2008	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 18/07/2008	**Overall study status** Completed	
Last Edited 21/08/2014	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Study information

Scientific Title

Study objectives

The purpose of this study is to assess the effectiveness, for individuals who experience a first "mild" stroke, of a sustainable, low cost, multimodal support intervention (comprising information, education and telephone support) - "WE CALL" compared to a passive intervention (providing the name and phone number of a resource person available if they feel the need to) - "YOU CALL", on two primary outcomes: unplanned-use of health services for negative events and quality of life. Secondary outcomes include participation level, depressive symptoms, and planned-use of health services for health promotion and secondary prevention.

A secondary objective is to explore contribution of potential explanatory variables such as age, gender, living alone versus with a significant other, comorbidity level and access (or not) to a secondary stroke prevention clinic, on outcomes. We hypothesise that the provision of the "WE CALL" intervention over the first six months post-stroke, compared to the "YOU CALL" will result in:
1. A decreased unplanned-used of health services for negative events
2. An improved quality of life
3. Less depressive symptoms, a better participation in daily activities and social roles, and an increase in planned health visits for promotion and secondary stroke prevention all persisting six months beyond the intervention period
4. Participants with higher comorbidity level will benefit more from the active intervention given the increased complexity of their health status and
5. Participants with access to secondary stroke prevention (SPC) clinic will benefit more from the intervention than those without SPC access

On 09/02/2009 the trial start and end dates of this record were updated. The initial dates at the time of registration were:
Initial anticipated start date: 01/10/2008
initial anticipated end date: 01/05/2011

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Ethics Board of Chatham Kent Health Alliance, Ontario, 01/10/2008, ref: 08SE002
2. Ethics Board of Grand River Hospital, Kitchener-Waterloo, Ontario, 01/12/2009, ref: THREB #08-213
3. Ethics Board of Brant Community Health Care System, Brantford, Ontario, February 2009
4. Ethics Board of Calgary site in Alberta, January 2009
5. Ethics Board of CRIR establishments for the province of Quebec, 21/01/2009, ref: CER # 373

Primary study design
Interventional

Study design
Randomised single-blind clinical trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Mild stroke rehabilitation

Interventions

Active experimental group:
A multimodal (telephone, internet and paper) support intervention will be provided to participants randomly allocated to the experimental active "WE CALL" group. The telephone component of the intervention will be based on the Family Intervention Telephone Tracking model (FITT). The FITT focuses on reinforcing problem solving skills through counselling and favours the use of available community resources. Issues pertaining to secondary prevention and adaptation are included. Each telephone interaction will focus on any new, or ongoing issues as well as six key areas:
1. Family functioning
2. Depression
3. Neurocognitive functioning
4. Functional independence
5. Physical health
6. Individualised risk factors

To ensure quality and reproducibility in the provision of the intervention, the FITT model has a well-developed manual and a clinician guide with an alphabetical listing of issues, clinical importance, and suggested interventions. Although the FITT model was initially developed to be offered to both members of the family (the individual who has experienced a stroke and their carer), telephone contacts are made on an individual basis, making it highly usable with only the individual who has experienced the stroke. We chose not to include caregivers in this trial given both the important proportion of individuals living alone as well as the lack of clear evidence of mild stroke consequences on the family. The FITT is currently successfully used on an individual basis, with caregivers of patients with Alzheimer's disease. Upon requests from the participants, Trained Health Care Professional (THCP) will discuss specific issues also with the spouse. Before trial commencement THCPs providing the intervention will be rigorously trained by DB and AR, and weekly debriefings during the course of the study will be lead by AR.

Concretely, participants will be asked how they are doing with the six key areas. For example, when discussing functional capacity, one important issue could be driving. Did they receive any advice in regards to driving? Do they have the required abilities to drive safely? Do they need an assessment or re-training? As an intervention, they could be referred to the StrokEngine module specifically on driving after a stroke (via internet or through hard copies) and specific concerns could be individually discussed over the phone. Each specific issue is addressed during the next call to ensure active involvement. Participants of this group will be called by the THCP on a weekly basis for the first two months, bi-weekly during the third month, and monthly for the last three months of the intervention. It is estimated that each intervention call should last between 15 - 20 minutes. Participants will be encouraged to contact the THCP between intervention calls, should they feel the need to. If the THCP is unavailable, the participant will be invited to leave a voice message and the THCP will contact them within the day, with the exception of weekends. The frequency and content of these additional calls will be documented.

Additional written information will be provided when and as needed. Providing information at the time it is most relevant increases its effectiveness. Participants will be referred to local community services as necessary and/or directed to their family doctors when they experience health problems (including depression). Written information on secondary stroke prevention and effectiveness of rehabilitation interventions post-stroke will be made available either directly via an Internet website - StrokEngine - or through CDs or paper copies, for those who do not have easy access to the Internet or a computer. Use of well developed information packages on the benefits of smoking cessation, regular exercise, and adopting a healthy diet, will also be made available.

Passive experimental group:
Participants allocated to the experimental passive "YOU CALL" group will be provided with the name and phone number of a THCP who is not involved in providing the "WE CALL" intervention, whom they are free to contact should they feel the need to. This THCP will be different from the ones providing the intervention to the "WE CALL" group to minimise potential contamination between the interventions (active and passive) due to THCPs. THCP-passive will be instructed to provide only information on topics initiated by the participant. He/she will be instructed to provide complete information to adequately answer participants' requests but will not probe on other issues. The use of this passive intervention as a control, which is very ecological (most individuals are provided with stroke information pamphlets and phone numbers to contact), is more acceptable ethically than a "pure" control group receiving no intervention (or only usual care) and provides some control for the Hawthorne effect.

For both groups, frequency and content of each call will be documented. To ensure consistency of intervention adherence over time by the THCPs (both active and passive), the principal investigator will listen 10% of the calls at randomly chosen period where only the THCP will be heard and not the participant. We are aware that internet is a public resource available to all members of the community. It is not the goal of the study to "control" all information potentially provided to participants. We aim to control and prevent bias while remaining as ecological as possible; i.e. assess the added value of a systematic follow-up.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
1. Unplanned-use of health services and planned-use will be identified as:
1.1. Number of doctor visits, emergency or medical clinic visits
1.2. Number of hospitalisations and any other use of other health care professionals (e.g. social worker, psychologist, physical therapist, occupational therapist, etc.)
For the six-month period of the study and an additional six months follow up period, assessed at three months, six months, nine months and one-year. To minimise recall bias, these data will be collected by way of a frequency calendar where each participant will note the health services they used, reasons (e.g. a fall, dizziness, stroke, follow up appointment, physical therapy, etc.) and most importantly if the visit was planned (scheduled) or not (emergency). At the time of data coding, each entry will be scrutinised by three stroke specialist health professionals, not involved in the study, to differentiate noise (such as emergency for a cold or planned-visits for foot care) versus any stroke-related use of the health care system (e.g. emergency for a fall, dizziness, or follow up visit for hypertension or any other risk factors) upon which the program aims to have an effect. Each entry will be dichotomised as either planned for health promotion /prevention or unplanned for a negative event.
2. The 32 item questionnaire Quality of Life Index (QLI), which was developed from Ferran's conceptual model of quality of life and which has been used repeatedly with a stroke clientele was chosen as the primary outcome. Each item of the QLI as relating to four life domains (health and functioning, socio-economic, psychological/spiritual and family), is evaluated in terms of satisfaction and importance on a six-point scale. Scores for each domain and a global score are expressed from 0 to 30, a higher score indicating a better quality of life. This will be assessed at baseline, three months, six months and one-year follow up.

3. The EQ-5D composed of 5 items rated on a three-level scale will also be completed as this questionnaire provides utility estimates needed to performed cost-utility analysis. This will be assessed at baseline, three months, six months and one-year follow up.

Key secondary outcome(s)
1. The LIFE-H will be used to measure the ICF participation domains. This questionnaire is composed of 77 items and covers 12 domains of participation. The first six domains: nutrition, fitness, personal care, communication, housing, and mobility refer to the accomplishment of daily activities whereas the last six: responsibilities, relationships, community life, education, employment and recreation refer to the accomplishment of social roles. Participants are asked about the degree of difficulty in accomplishing the activity or the social role (without difficulty, with difficulty, by substitution or not realised) as well as assistance used (technical assistance, physical arrangements or human help). From their answers to those two simple questions, scores for each domain and global score are derived and expressed from 0 to 9 where a higher score indicates a better participation. It takes between 20 - 30 minutes to administer. The "WE CALL" intervention, through support and information about available community resources, is expected to foster improvements in many different domains of community re-integration covered with the LIFE-H, especially in regards to social roles domains.
2. Depression will be measured using the Beck Depression Inventory II (BDI-II) created to correspond with the updated Diagnosis of Diagnostic and Statistical Manual of Mental Disorders, 4th edition (DSM-IV) criteria for depression. It is still composed of 21 items answered on a four-point Likert scale (score ranging 0 - 63) with a higher score indicating a greater severity of depression. A score of 0 - 13 is considered none or minimal range depression; 14 - 19 mild depression; 20 - 28 moderate depression; and 29 - 63 severe depression.

Secondary outcomes measured at baseline, six months and one-year follow up.

Completion date
01/12/2010

Eligibility

Key inclusion criteria
1. Adults (greater than 18 years of age), male or female
2. Have sustained a first "mild" stroke defined as:
2.1. A score greater than 8.5 on the Canadian Neurological Scale, OR
2.2. A Modified Rankin Scale score 0 to 2, OR
2.3. Ability to accomplish basic activities of daily living

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Individuals who are unable to communicate in English or French
2. No telephone access

Date of first enrolment
01/12/2008

Date of final enrolment
01/12/2010

Locations

Countries of recruitment
Canada

Study participating centre
School of Rehabilitation
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Sponsor information

Organisation
Canadian Stroke Network (Canada)

Funder(s)

Funder type
Research organisation

Funder Name
Canadian Stroke Network (Canada)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2013		Yes	No
Protocol article	protocol	06/01/2010		Yes	No