

Enhancing Recruitment Using Teleconference and Commitment Contract (ERUTECC): a stepped wedge cluster randomised trial within the EFFECTS trial

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Research

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Abstract

Background: Two out of three randomised controlled trials fail to meet their recruitment goals. Recruitment to EFFECTS, a trial of fluoxetine for stroke recovery was slower than anticipated. We aimed to evaluate an intervention to improve recruitment to EFFECTS.

Methods: We performed a stepped wedge, cluster randomised trial embedded in the ongoing EFFECTS trial. The Enhancing Recruitment Using Teleconference and Commitment Contract (ERUTECC) comprised a structured teleconference with the study personnel and the head of department supplemented by a commitment contract. ERUTECC's primary outcome was the number of patients recruited into EFFECTS per 60 days per site. We compared the recruitment 60 days before the intervention with 60 days after and considered at least a 20% increase to be a positive outcome. All centres started as controls and were followed by 60 days observation. The order in which the centres began was decided through block randomisation.

Results: At randomisation, EFFECTS had 29 active centres. ERUTECC recruited 20 centres between 9th Nov 2017 and 30th June 2018, providing 80 site months of observation for the primary analysis.

The inclusion rate was 1.9 patient/centre/60 days before the intervention and 2.1 patient/centre/60 days after the intervention, representing a 10% overall increase. However, the recruitment increased more than 20% the first 30 days after the intervention. We also noted that inclusion rate increased directly after the first contact with the centres, announcing a future telephone conference. Some centres changed their screening process, transferring the task from doctors to nurses.

Conclusions: Although a teleconference with the study personnel and the head of department accompanied by a commitment contract did not increase recruitment to an RCT by more than 20%, 60 days post intervention, recruitment improved during the first month, especially at low-recruitment centres.

Trial registration : The ERUTECC study was registered in the Northern Ireland Hub for Trials Methodology Research Studies Within a Trial Repository (SWAT58) 30 April 2017.

<https://www.qub.ac.uk/sites/TheNorthernIrelandNetworkforTrialsMethodologyResearch/SWATSWARInformation/Repositories/SWATStore/>

EFFECTS was retrospectively registered 2 February 2016 in ClinicalTrials.gov: NCT02683213.

Background

Introduction

Recruitment failures are incompletely understood. This is probably of when they occur, the trial management try to do their best to improve recruitment, making it hard to know what has made the difference [4-6]. Possible barriers are lack of time, resources or experience. Other contributing factors are competing trials and a study protocol that is difficult to implement in the daily routine at the clinic.

Despite the fact that several trials have explored possibilities to enhance recruitment [7-9], surprisingly few have proven to be generalisable [10]. Among things that have been tested are closer contact with the coordination centre by telephone or emails, individual feedback on recruitment, re-visits to review the trial protocol or other educational packages, changes in the consent process, and financial incentives; all with marginal effects on recruitment [10].

Aim

The aim of the intervention, Enhancing Recruitment Using Teleconference and Commitment Contract (ERUTECC) was to investigate whether a teleconference including a structured content with the study personnel and the head of department accompanied by a commitment contract can enhance recruitment in the EFFECTS-trial 60 days post intervention, compared to 60 days pre-intervention.

Methods

Setting

This trial was an embedded study within Efficacy of Fluoxetine - a randomised Controlled Trial in Stroke (EFFECTS), an RCT of fluoxetine for stroke recovery [13]. Briefly, EFFECTS included stroke patients 2-15 days after stroke from 35 centres in Sweden (28 acute stroke units, 5 rehabilitation centres and 2 geriatric rehabilitation centres). The primary objective of EFFECTS was to evaluate whether 20 mg fluoxetine would improve functional outcome at 6 months. Recruitment started 20 October 2014 and ended 28 June 2019, when the target of 1500 patients was met. The original recruitment goal was that each centre should randomise at least two patients per month, but as the study progressed, we discovered a huge discrepancy between centres; 7 out of 35 centres recruited half of the patients. This pattern, that a few centres have included

the majority of subjects, was consistent during the trial. Although we managed to recruit about 30 patients per month, we noticed a certain decline in inclusion over time which could jeopardise funding. There was therefore an urgent need to improve recruitment into the trial

Centre recruitment

The EFFECTS trial included 1500 patients between 20th Oct 2014 and 28th June 2019 and had at most 35 centres. When ERUTECC started 9th Sep 2017, we had closed 6 centres for administrative reasons. Hence, there were 29 active centres in EFFECTS at the start of the intervention (Figure 1). We excluded the 5 top-recruiters (centres that recruited ≥ 2 patients/months) since we believed that they had reached their full potential and the intervention would be too weak for them. Two centres were closed between randomisation and the intervention (administrative reasons), and two centres declined to participate, leaving 20 centres for the intervention (Figure 1).

*Insert Figure 1 here. File name: Figure 1 CONSORT flow diagram for the Enhancing Recruitment Using Teleconference and Commitment Contract (ERUTECC) trial. ERUTECC is a randomised stepped wedge trial within the EFFECTS trial.pptx

We used a stepped wedge cluster design [14, 15], i.e., all centres received the intervention but at different times. By the end of the study, all participants had received the intervention, although the order in which participants receive the intervention was determined at random.

The 20 centres were divided into two categories: low and medium recruiters. We categorised the centres according to their average recruiting/month during an 18 months observation period between 1 March 2016 and 30 Aug 2017, into three levels: low (< 0.5 patients/month), medium (between 0.5-2.0 patients/month), and high recruiter (> 2 patients/month). The rationale for dividing centres into low- and medium recruiting was that we did not want to risk that all medium recruiting centres should fall into the same step, i.e. summer period, which is usually a low-recruiting period in Sweden. Another reason was that we suspected that the intervention might have different effects on low recruiters compared to medium centres. The statistician used stratified block randomisation in each group to allocate the 20 centres into 10 groups of two or three centres per step, leading to (at least) one medium and one low recruiting centre in each step. Because two centres were closed between randomisation and the intervention, two groups finally consisted of one centre. The time at which the centres started the intervention was randomly allocated. Every step consisted of 1-3 centres as shown in Figure 2.

**Insert Figure 2 here. File name: Figure 2. The ERUTECC stepped wedge trial design. M= medium recruiting centre and L= low recruiting centre. The yellow colour is two months before the intervention for each step, the blue colour is 60 days after the observation, and the red vertical bar indicates the time of the intervention.docx

Details of the teleconferences

Each centre was invited by email to the conference one month in advance (median 35 days). One week before the meeting an email with the attached agenda and a PowerPoint-presentation was sent to all participants (see Additional file 1). The meeting comprised a presentation of EFFECTS; background, rationale, aim and update of recruitment. The discussion was related to barriers to recruitment at the local site with study personnel and the head of department and what could be done to increase recruitment. Full details of the intervention can be found in the published ERUTECC protocol [16]. To encourage recruitment, the Chief Investigator (EL) and the Trial Manager (EI) conducted the teleconference with the principal investigator and the trial team at each centre as well the head of department.

The centres estimated how many patients they assumed they could randomise in the future and formulated a commitment contract regarding goals for recruitment that was duly signed. Our hypothesis was that a commitment contract would make the personnel put more effort into the intervention.

Before starting the intervention, we had a run-in period during which we measured how many patients each centre recruited over a 60-day period. We chose 60 days because many centres recruited small numbers of patients, 0-1 patients/months, and we estimated that a shorter period would lead to overly small numbers, and random variations.

Outcomes

The primary outcome was the recruitment rate in the EFFECTS-trial 60 days post the ERUTECC intervention, compared with 60 days pre-intervention. Secondary outcomes were to compare the effect of the intervention on recruitment rates in:

1. Low- versus medium recruiting centres (according to their average recruiting/month in an 18 months observation period between 1 March 2016 and 30 Aug 2017)
2. Small versus large (>500 stroke/year) stroke units
3. Stroke units versus rehabilitation clinics
4. University hospitals versus non-university hospitals
5. Experienced centres versus non-experienced centres. (An experienced centre was defined as a centre where both the investigator and the study

nurse had been involved in five or more trials or had carried out their own research).

6. Recruitment rate 61–120 days post teleconference compared with 61-120 days pre- intervention.

Exploratory, we compared the recruitment 30 day before with 30 days after the intervention (post-hoc analysis).

The participants were not informed about the aim of ERUTECC or that the timing of the intervention was randomised or that we measured numbers of randomised patients before and after intervention, but they were fully aware of the fact that we wanted to enhance recruitment. The exact numbers of recruitment per centre were available at the public domain through a link that was updated in real time since the start of the EFFECTS study [17].

Statistical methods

For the primary outcome, we compared the numbers of included subjects 60 days before intervention with the numbers of subject 60 days post intervention. The null hypothesis was that there is no difference before and after. We considered a 20% increased recruitment rate as being a positive outcome. For the secondary outcomes, we compared the difference between the recruitment rates before and after intervention in the same way.

Results

We had one or two teleconferences every month between 9th September 2017 and 30th August 2018 and ended when all available centres had their intervention. The intervention did not improve the recruitment rate of 20% or more in EFFECTS. The inclusion rate before the intervention was 1.9 patients/centre/60 days and the inclusion rate after the intervention was 2.1 patients/centre/60 days, which is an increase in recruitment of 10%. However, the inclusion of patients increased by 78%, 24% and 20% among the low recruiting, small, and non-university centres respectively the first month after the intervention (Table 1).

Table 1 Primary and secondary outcome within 60 days before and after the intervention

	Before	After	Difference	Improved patient recruitment of at least 20%
Primary outcome measured within 60 days				
All centres (n=20) patients/60 days	39	43	4 (10%)	no
Secondary outcomes measured within 60 days				
Low recruiting centres (n=9) patients/60 days	9	16	7 (78%)	yes
Medium recruiting centres (n=11) patients/60 days	30	27	-3 (-10%)	no
Small stroke units (n=13) patients/60 days	25	31	6 (24%)	yes
Large stroke units (n=4) patients/60 days	9	9	0 (0%)	no
Stroke units (n=17) patient/60 days	35	40	5 (14%)	no
Rehabilitation units (n=3) patients/60 days	5	3	-2 (-40%)	no
University hospitals (n=4) patients/60 days	9	7	-2 (-22%)	no
Non-university hospitals (n=13) patients/60 days	30	36	6 (20%)	yes

Table 1 Primary and secondary outcome measured by 60 days before and 60 days after the intervention. Before indicates the numbers of patient included 60 days prior to intervention. After indicates the number of patients included 60 days following the intervention. More than 20% was defined as a positive outcome.

In a post-hoc analysis we found that recruitment increased within 30 days, especially among low recruiting centres, but also amongst small stroke units and non-university hospitals (Table 2).

Table 2 Explorative outcomes within 30 days before and after the intervention

Explorative outcomes measured within 30 days	Before	After	Difference	Improved patient recruitment of at least 20%
All centres (n=20) patients/30 days	22	27	5 (23%)	yes
Low recruiting centres (n=9) patients/30 days	4	10	6 (150%)	yes
Medium recruiting centres (n=11) patients/30 days	18	17	-1 (-6%)	no
Small stroke units (n=13) patients/30 days	13	19	6 (46%)	yes
Large stroke units (n=4) patients/30 days	7	6	1 (-14%)	no
Stroke units (n=17) patients/30 days	20	25	5 (25%)	yes
Rehabilitation units (n=3) patients/30 days	2	2	0 (0%)	no
University hospitals (n=4) patients/30 days	7	6	-1 (-14%)	no
Non-university hospitals (n=13) patients/30 days	13	19	6 (46%)	yes

Table 2. Explorative outcomes measured by 30 days before and 30 days after the intervention. Before indicates the numbers of patients included 30 days prior to intervention. After indicates the numbers of patients included 30 days following the intervention. More than 20% was defined as a positive outcome.

The recruitment increased among the low recruiting centre (7 patients/60 days) but decreased among the medium recruiting centres (-3 patients/60 days) (Figure 3).

***Insert Figure 3 here. File name: Figure 3. Change in recruitment for low- and medium recruiting centres 60 days before recruitment.docx

There was great variability in recruitment rates between the low-recruiting centres. One centre increased from 1 patient/month to 9, and one decreased from 4 to 0/month.

In addition, we noticed that the inclusion rate increased after the first contact with each centre announcing a future telephone conference.

Changes in work practices

During the teleconference, several things were highlighted. Study personnel at all centres considered EFFECTS's research question to be important.

After the conference some centres changed their ways of working: the screening of patients was performed by the nurses instead of the doctors, other tasks related to the study (different scales, randomisation process) were also transferred to an experienced nurse instead of a doctor, and most centres decided to make the study more visible by displaying a poster on the ward and information meetings for others working at the hospital.

Discussion

Although a teleconference with the study personnel and the head of department accompanied by a commitment contract did not enhance recruitment by more than 20% in the EFFECTS trial 60 days post intervention compared to 60 pre-intervention, recruitment increased among the low recruiting, small, and non-university hospitals. One possible reason why we saw an increase among the smaller hospitals was that they changed their organisation. For example, a low recruiting centre started by organised screening done by research nurses three times a week.

One thing that emerged in our study was that changed work routines could increase recruitment. An important alteration for several centres involved in the intervention was to increase the number of people working with the study and assign more tasks related to the study to an experienced nurse. A proposed alternative in the literature to make trials more efficient in recruiting is to have a screening list. EFFECTS had screening logs and urged the study personnel to update them on regular basis but did not required centres to send the list to the co-ordination centre (sponsor) at Danderyd Hospital. However, the important thing is to regularly identify and discuss potential patients, not the filling in of a screening list [18]. Therefore, it is important to have a dedicated and organised research team with daily routines for doing research. Dedicated clinical trial nurses are in an ideal position to coordinate the identification of potential participants, ensure that eligibility criteria are met and together with the study physicians be responsible for the details of recruitment and that enrolment is done efficiently. To better plan and find suitable patients, nurses need time to develop strategies to search for eligible patient [19, 20].

We decided to invite the heads of department to the teleconference to strengthen the intervention, since they are responsible for the allocation of time and resources. However, this did not have any impact on the overall recruitment.

Our results showed that a phone call to the local centre, announcing a future conference, increased recruitment. This is in line with previous studies that have shown that regular contact with the study team increase recruitment [6, 21, 22]. Our results suggest that it is important to show that you care about the study and the person with whom you are communicating in order to maintain the commitment and to move the clinical trial forward.

A strength of our embedded recruitment trial is the stepped wedge randomised design. The design allowed us to carry out the intervention at all centres at the same time. We believed that all centres could benefit from the intervention, and in a stepped wedge design all centres are exposed. Every cluster provides before and after observations, and every cluster switch from being control to becoming exposed to the intervention, but at different times. Finally, we could avoid the seasonal variation in recruitment that we had noted, and the result were not affected by that recruitment decrease around Christmas, Easter, and especially in the summer.

It appears in our study that enthusiasm for a trial fades quickly, the effect of the intervention was short-lived (30 days) and did not last over a 60-day period. Regular contact from those leading the trial is of importance, this has also been shown by Fletcher et al [8]. We chose 60 days as the time for the primary outcome since we suspected that a 30-day observation would be too short. Given the results, it would have been wiser to choose a shorter time frame.

Another way to maintain the enthusiasm for recruiting subjects to a trial is to make the study visible at the hospital by setting up posters but also by regularly reminding of and talking about the study at meetings, on rounds and with patients and relatives. The fact that patients have a greater awareness of their own health problem and that the potential impact a clinical trial could have on their health could increase recruitment, has also been described by Caldwell et al [23].

Our study has some limitations that may have influenced the results. Firstly, since we began, the EFFECTS-trial we had regular contact with most of the centres, working hard to stimulate study personnel to find and include patients. We have consistently tried to identify barriers and find ways to enhance recruitment and there is a possibility that we have reached a ceiling effect in this regard and the intervention might have been too weak to achieve positive results. Ultimately, we have tried to change the behaviour pattern for over 60 persons, and behaviour change is one of the hardest things to accomplish. Originally, we planned to send text reminders via SMS to each examiner, but no participants in the trial accepted this.

Secondly, we might be criticised for not including the top recruiting centres in ERUTECC. However, we believe that high recruiting centres have reached their maximum recruitment and that the intervention only has a minor effect. The fact that medium recruiting centres did not improve their inclusion strengthened that assumption.

Thirdly, the intervention might evolve during the study. For example, the agenda or the content of the teleconference might change during the study period. Participants in the host study (EFFECTS) might get to know about the intervention and change their behaviour before the planned intervention.

Finally, two centres declined to be a part of the intervention and this could have impacted the results. One of them increased their recruitment rate after being invited to participate in the intervention and that is not in our results. Two centres were closed for administrative reasons before the intervention was initiated. The local PI lacked motivation and for a long time had failed to include any patients. If we had managed to entuse them, maybe the outcome would have been different.

Conclusions

A teleconference with the study personnel and the head of department together with commitment contract did not increase recruitment to more than 20% in an RCT 60 days post intervention. However, recruitment did increase the first month, especially at low-recruitment centres.

Declarations

Ethics approval

EFFECTS has approval from the central ethics committee in Stockholm (reference 2013/1265–31/2), this study ERUTECC 2017/1285-31/1 was approved on 9th August 2017. Since the participants in the telephone meeting were already in the EFFECTS study, they may have felt compelled to be included in this study as they may have experienced that they were in a position of dependency. This can be beneficial for study staff at the local centre in getting support and help in finding strategies to reach their goal and in including patients in the study they have already accepted participation in.

Consent for publication

Not applicable

Availability of data and materials

The dataset for this study will be made available by the corresponding authors on reasonable request.

Competing interest

The authors declare that they have no competing interests.

Funding

This study was conducted within the funding for the EFFECTS study. Currently EFFECTS is given grants by the Swedish Research Council, the Swedish Brain Foundation, the Swedish Heart-Lung Foundation, King Gustav V and Queen Victoria's Foundation of Freemasons, the Swedish Stroke Association (STROKE-Riksförbundet) and the Swedish Society of Medicine. None of the funders had any influence over the planning, performance or interpretation of the study.

Authors contributions

All authors took part in designing the study. EI and EL reviewed the literature, administered all conferences. EI wrote the first draft of the manuscript. PN was responsible for the statistics and all authors took part in the evaluation of the results. All authors made substantial contributions to the paper and the concepts presented in the manuscript have been developed by all the authors. All authors have read and approved the final version of the manuscript.

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Abbreviations

EFFECTS: Efficacy of Fluoxetine – a randomised Controlled Trial in Stroke; ERUTECC: Enhancing Recruitment Using Teleconference and Commitment Contract;

RCT: Randomised controlled trial; SWAT: Study Within a Trial repository; CONSORT: Consolidated Standards of Reporting Trials

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Supplementary Information

Additional file 1. Presentation for the teleconferences.pptx PowerPoint presentation used for all the teleconferences with a presentation of EFFECTS; background, rationale, aim and update of recruitment.

Figures

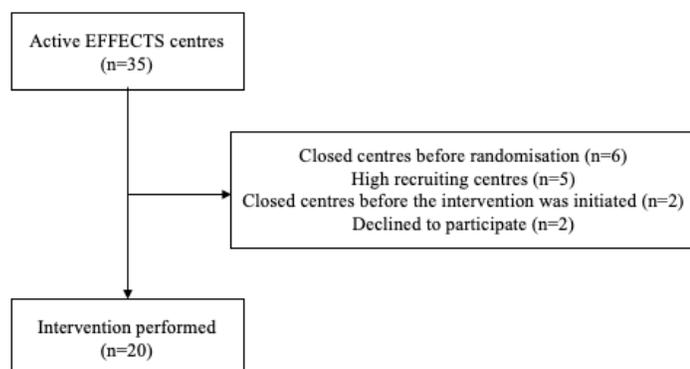


Figure 1

CONSORT flow diagram for the Enhancing Recruitment Using Teleconference and Commitment Contract (ERUTECC) trial. ERUTECC is a randomised stepped wedge trial within the EFFECTS trial.pptx

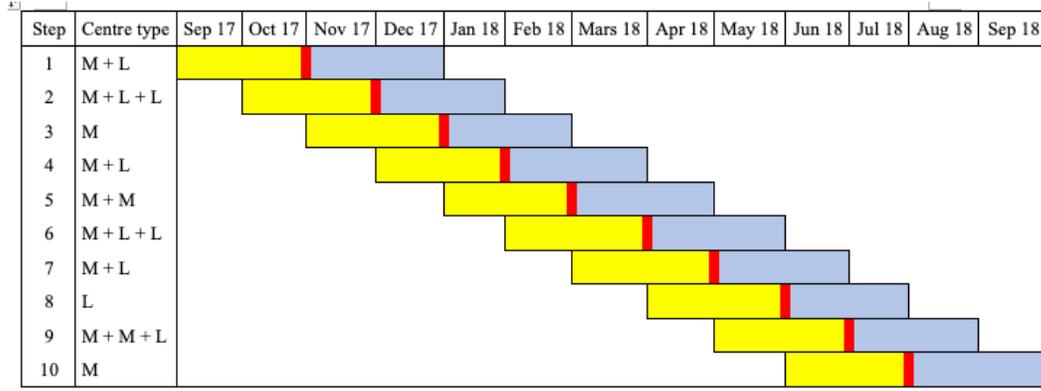


Figure 2

The ERUTECC stepped wedge trial design. M= medium recruiting centre and L= low recruiting centre. The yellow colour is two months before the intervention for each step, the blue colour is 60 days after the observation, and the red vertical bar indicates the time of the intervention.docx

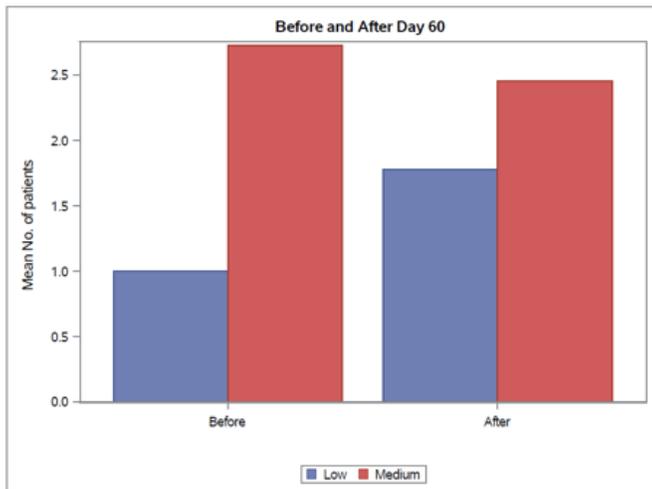


Figure 3

Change in recruitment for low- and medium recruiting centres 60 days before recruitment.docx

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- [Additionalfile1.Presentationfortheteleconferences.pptx](#)
- [CONSORTERUTECC.docx](#)