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Use of scratchcards for allocation concealment in a prehospital randomised controlled trial

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ABSTRACT

Background Rapid Analgesia for Prehospital Hip Disruption was a small study designed to determine the feasibility of undertaking a randomised controlled trial (RCT) to test the clinical and cost-effectiveness of paramedics administering Fascia Iliaca Compartment Block as early prehospital pain relief to patients with a fractured hip. The objective was to devise a simple and effective method of random allocation concealment suitable for use by paramedics while in the emergency prehospital setting.

Methods Scratchcards were produced using scratch-off silver stickers which concealed the trial arm allocation. Paramedics were each allocated a unique range of consecutive numbers, used as both the scratchcard number and the patient's study ID. The cards were designed to allow the paramedic to write on the incident number, date and signature. A small envelope holding the cards was prepared for each paramedic. The study took place between 28 June 2016 and 31 July 2017 in the Swansea area.

Results Nineteen trial paramedics used 71 scratchcards throughout the study and reported no problems randomly allocating patients using the scratchcards. Five protocol deviations were reported in relation to scratchcard use. On auditing the scratchcards, all unused cards were located, and no evidence of tampering with the silver panel was found.

Conclusion Paramedics can use scratchcards as a method of randomly allocating patients in trials in prehospital care. In the future, a method that allows only the top card to be selected and a more protective method of storing the cards should be used. Scratchcards can be considered for wider use in RCTs in the emergency prehospital setting.

Trial registration number ISRCTN60065373; Post-results.

INTRODUCTION

Generation of an unpredictable randomised allocation sequence represents the first crucial element of randomisation in a randomised controlled trial (RCT).¹ Following this, the randomised allocation sequence must be concealed until required. Allocation concealment ensures that the treatment to be allocated is not known before the patient is entered into the study, thus preventing selection bias.² The Rapid Analgesia for Prehospital Hip Disruption (RAPID) study was a feasibility study to test the methodology for a multicentre RCT looking at clinical and cost-effectiveness of paramedics administering Fascia Iliaca Compartment

Key messages

What is already known on this subject

▶ Various methods of random allocation concealment are available; however, none were considered robust enough to be used by paramedics while carrying out their duties on an emergency ambulance.

What this study adds

▶ Our study is the first to report on the use of scratchcards for random allocation concealment in a randomised controlled trial by paramedics. We also discuss how the method may be improved for future trials.

Block as early pain relief to patients who have a fractured hip at the scene of injury.³ When considering methods of allocation concealment, sealed envelopes were thought to be too bulky for the paramedics to carry around on shift and too easy to tamper with. Owing to a paramedic's shift patterns, randomisation by radio, telephone or email needed to be available 24/7; this was not feasible due to cost, unpredictable phone signal and internet access. The method selected needed to reduce the time delay in allocating the patient to either trial arm so that they could receive analgesia quickly. The use of scratchcards been used successfully in the past,⁴⁻⁶ though not in prehospital care, to our knowledge. This short report describes the experience of using scratchcards in this study.

METHODS

RAPID used individually issued, sequentially numbered scratchcards to randomly allocate patients to trial arms. In order to devise a simple and effective method of concealment, we purchased scratch-off silver stickers and perforated standard Avery sheets of business-sized cards and created our own scratchcards. The paramedics were allocated a unique range of consecutive numbers which was used as both the scratchcard number and the patient's unique study ID. The cards were designed to allow the paramedic to enter by hand the incident number, date and a signature (figure 1). A small 'dinner money' style envelope holding 10 cards was prepared for each paramedic, showing their name and the card number range within it. We used a fixed block size of two, stratified by a paramedic, to ensure that as long as each randomised



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Figure 1 Scratchcards with silver foil panel, unique card number and details to be entered by a trial paramedic.

two patients, they would have the opportunity to carry out the intervention.

We required the 19 trial paramedics to carry the cards on all of their operational shifts during the study which took place between 28 June 2016 and 31 July 2017 in the Swansea area.

When attending a patient eligible for randomisation, we advised that they scratch the card with a finger nail, out of sight of the patient.

Following the completed patient case, the completed scratchcard was returned to a locked cupboard on the ambulance station and a randomisation log completed. From here, the scratchcard was collected by the Research Support Officer (RSO) and returned to the Trials Unit.

The scratchcards were audited by the RSO mid-way through the trial to ensure that the correct number of cards remained, and that the silver panels remained intact, indicating that they had not been tampered with. They were audited again when patient recruitment had closed, and all remaining scratchcards had been received by the trial office.

We included questions about the use of scratchcards in paramedic focus groups which were conducted during the trial.

RESULTS

Nineteen participating trial paramedics used 71 scratchcards on eligible patients between 27 June 2016 and 31 July 2017.

There were five protocol deviations reported in relation to the scratchcards (table 1).

One trial paramedic reported his scratchcards as irreversibly damaged as his cards were accidentally left in his uniform pocket and placed in a washing machine. Duplicate cards were produced and reissued.

Table 1 Protocol deviations related to scratchcard use

No of protocol deviations	Deviation
1	Date of randomisation and paramedic signature not written on the scratchcard
1	Scratchcard selected out of sequential order in an attempt to get an intervention card
3	Paramedic accidentally used scratchcard from back of pack instead of from the front

Audit of scratchcards showed no evidence of tampering with the silver panel.

All paramedics reported that the scratchcard envelopes become worn within a few months of the trial starting. As a result, more sturdy envelopes were produced, and the originals were replaced.

On specific questioning in focus groups towards the end of the recruitment period for RAPID, the trial paramedics reported no problems randomly allocating patients using the scratchcards and found them simple to use.

Paramedics supported the use of scratchcards to randomise patients. They said it was a simple approach which could be easily undertaken without interrupting patient care and treatment.

DISCUSSION

Randomisation of participants to treatments prevents selection bias in clinical trials.⁴ It was essential in this study that the treatment allocation was not known by the paramedic prior to randomisation to prevent them administering their perceived 'best' treatment. The method of concealment selected in this study proved robust enough to prevent this. Previous studies⁴ conclude that this method of randomisation could be used effectively in clinical trials as it offers the advantage of blinding both the researcher and the participant to the next allocation. Initially, we looked at outsourcing the production of scratchcards; however, given the number we required, the cost was prohibitive, and we created our own.

In order to overcome the issue of trial paramedics removing cards from the back of the pack rather than the front, we recommend using a pocket-sized dispenser, similar to the ones used for business cards, or that the scratchcards are made into a booklet where the front scratchcard can be torn off. A case would provide better protection to the cards and would also be bulkier, so it could reduce the risk of the cards being left in clothing and washed.

Although one paramedic scratched a card out of sequential order, it did not affect the number of allocations to intervention and control they would receive by the end of the study.

Since the RAPID study, scratchcards have been used successfully as a method of allocation concealment in another randomised controlled study investigating prehospital recognition and antibiotics for 999 patients with sepsis.⁷

CONCLUSION

Paramedics can safely and effectively use scratchcards as a method of allocation concealment in patients in trials in prehospital care. For future use, we would suggest using a more protective method of storing the cards and one that allows only the top card to be selected.

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