

Feasibility of a structured group education session to improve self-management of blood pressure in people with chronic kidney disease: an open randomised pilot trial

Jo Byrne,¹ Kamlesh Khunti,² Margaret Stone,² Azhar Farooqi,³ Sue Carr¹

To cite: Byrne J, Khunti K, Stone M, *et al.* Feasibility of a structured group education session to improve self-management of blood pressure in people with chronic kidney disease: an open randomised pilot trial. *BMJ Open* 2011;1:e000381. doi:10.1136/bmjopen-2011-000381

► Prepublication history and additional materials for this paper are available online. To view these files please visit the journal online (<http://bmjopen.bmj.com>).

Received 15 September 2011
Accepted 14 November 2011

This final article is available for use under the terms of the Creative Commons Attribution Non-Commercial 2.0 Licence; see <http://bmjopen.bmj.com>

¹Department of Nephrology, University Hospitals of Leicester NHS Trust, Leicester, UK

²Department of Health Sciences, University of Leicester, Leicester, UK

³East Leicester Medical Practice, Leicester, UK

Correspondence to

Dr Jo Byrne;
jo.l.byrne@uhl-tr.nhs.uk

ABSTRACT

Objectives: We aimed to test, at pilot level, a structured group educational intervention to improve self-management of blood pressure in people with chronic kidney disease (CKD). The current paper explores patient acceptability of the intervention.

Design: This was an open randomised pilot trial. Participants were randomly assigned to either:

- A control group (n=41) receiving standard clinical management of hypertension.
- An intervention group (n=40) receiving standard clinical care plus the educational intervention.

Setting: Renal outpatient clinics at a single study centre.

Participants: Patients with early CKD and hypertension were identified and approached for recruitment.

Intervention: An evidence-based structured group educational intervention (CHEERS) using the principles of social cognitive theory to improve knowledge and self-management skills.

Outcomes: Recruitment, uptake of the intervention and patient satisfaction were evaluated to explore patient acceptability of the intervention and to determine any differences between patients regarding recruitment and retention.

Measures: Data on age, sex and ethnicity were collected for all patients approached to take part. For recruited patients, data were also collected on self-efficacy (ability to self-manage). Reasons given by patients declining to take part were recorded. Patients attending the educational session also completed an evaluation form to assess satisfaction.

Results: A total of 267 patients were approached, and 30% were randomly assigned. Lack of time (48%) and lack of interest (44%) were the main reasons cited for non-participation in the study. Men were significantly more likely to be recruited (p=0.048). The intervention was rated enjoyable and useful by 100% of participants. However, 37.5% of the intervention group failed to attend the educational session after recruitment. Participants failing to attend were significantly more likely to be older (p=0.039) and have lower self-efficacy (p=0.034).

ARTICLE SUMMARY

Article focus

- Assessment of the feasibility of a complex educational intervention for people with kidney disease, focusing on patient recruitment, retention and satisfaction.

Key messages

- The paper highlights the importance of pilot work and the need to assess patient acceptability in the design of complex educational interventions for patients with kidney disease.
- Findings suggest the need to create, as part of routine kidney care, a culture of patient empowerment and education with continued support.
- The paper also suggests a need to identify those patients with CKD who lack motivation and confidence so that help and support can be tailored more effectively.

Strengths and limitations of this study

- The paper presents a robust evaluation of patient acceptability of a proposed structured group intervention to improve blood pressure control in people with CKD.
- A limitation of the study is the non-blinding of the patients and the evaluator due to the nature and practicalities of the research.
- Another limitation was the evaluation form used to assess patient satisfaction, which did not provide sufficient information to assess this outcome in more detail.

Conclusion: The findings suggest that delivering and evaluating an effective structured group educational intervention to promote better blood pressure control in patients with CKD would be challenging in the current context of kidney care.

INTRODUCTION

Educational interventions that empower patients to make decisions about their care

and obtain clarity about their goals, values and motivations are a relatively new approach to improving concordance in chronic diseases, and the importance of such interventions is increasingly being recognised.¹ However, it is not known whether such an approach will help to improve blood pressure (BP) control in people with early chronic kidney disease (CKD).

Structured education can teach people specific knowledge and skills to enable them to play an enhanced role in their care. A recent systematic review² of the effectiveness of structured education in kidney disease care identified only 22 randomised controlled trials (RCTs); and despite including only RCTs, methods generally were suboptimal, mainly because of poor reporting, small sample sizes, high dropout rates and inconsistency in the delivery of interventions. The interventions were aimed at predialysis and dialysis patients, with no interventions addressing early CKD (stages 1–3) or BP control. More educational interventions are needed in early CKD to help prevent the progression of kidney disease, and a major recommendation from this review is that rigorous evaluation of such interventions is essential to establish effectiveness.

Pilot studies are an essential part of this process, and the importance of robust pilot work to progressively refine the design of a complex intervention before embarking on a definitive trial has been highlighted in the Medical Research Council's guidance framework for the development and evaluation of complex interventions.^{3 4} The importance of assessing acceptability is an essential part of this process because if people will not accept an intervention, testing its potential effectiveness could be regarded as irrelevant. To understand acceptability, we need to look more closely at who we are recruiting for studies and interventions to determine possible reasons as to why people will choose or decline to participate. We can then modify and adapt our approach accordingly to increase the likelihood of delivering an effective intervention.

This pilot RCT (Controlling Hypertension: Education and Empowerment Renal Study (CHEERS)) involved a structured educational intervention, involving a group session, to improve self-management of BP in people with CKD (stages 1–4). The aims were to assess the acceptability of the intervention for a definitive trial to ascertain the effectiveness of the intervention for lowering BP and other cardiovascular risk factors and, if positively evaluated at pilot level, the intention was to further test the intervention in a definitive RCT comparing standard clinical care for BP management with standard care supplemented by the structured group intervention. The objectives of the study were as follows:

- ▶ To assess recruitment and retention rates for a definitive trial.
- ▶ To assess patient satisfaction with the proposed intervention to inform the design for a definitive trial.
- ▶ To increase our understanding of how to recruit patients more effectively by collating reasons given by

patients declining to take part in the study and by exploring the characteristics of these patients compared to those patients who agreed to take part.

- ▶ To increase our understanding of how to retain and engage patients more effectively by exploring the characteristics of the patients failing to attend the group session compared to those patients who attended the session.
- ▶ To assess the potential effectiveness of the proposed intervention on BP control and other cardiovascular risk factors for a definitive RCT.

The current paper focuses on patient acceptability of the proposed intervention with regard to recruitment, retention and patient satisfaction and the implications of these findings for the design of complex interventions for people with kidney disease.

METHODS

Participants, settings and location

Ethical approval was obtained from the local ethics committee (Ref: 06/Q2502/4), and participants were recruited from nephrology outpatients clinics at a single study centre (Renal Department, University Hospitals of Leicester NHS Trust, Leicester, UK). Patients with CKD (stages 1–4) had been referred (in line with clinical practice guidelines at the time) to secondary care for investigation and management of declining renal function. Patient invitations and information sheets were sent out prior to clinic visits, at which patients were approached by the study nurse to be consented for the study.

Suitable participants were identified for inclusion in the study if they had impaired renal function (estimated glomerular filtration rate ($eGFR$) <90 ml/min/1.73 m²) and sustained hypertension defined as BP above the recommended target (130/80 mm Hg if no proteinuria and 125/75 if proteinuria present) at two or more readings taken at clinic visits in the previous 6 months. Target BP was defined in accordance with the UK Renal Association's CKD guidelines, which were the current guidelines at the time.⁵ Pregnant women, patients unable to speak English, patients with end-stage kidney failure, patients unable to give informed consent and patients aged <18 years were excluded as the educational intervention was not designed to meet their needs.

The study interventions

Patients were randomly assigned to one of the following two groups:

1. The control group received standard clinical management of hypertension. This involved participants being seen by a doctor in the outpatient clinic or by their general practitioner for measurement and management of BP.
2. The intervention group received the structured CHEERS patient education intervention plus routine standard care as above.

After randomisation, the patients assigned to the CHEERS educational intervention received a leaflet on

the management of hypertension. This was intended as a preparatory component to the education session so that participants would have some knowledge of high BP and be able to contribute to the facilitated discussions that would form the major part of the teaching in the educational intervention.

Initial development of the CHEERS intervention involved identifying a suitable theoretical framework to structure the intervention and the use of key findings from preliminary focus groups to involve both patients and health professionals in developing the content and design. Participants from the patient focus group identified a need for basic knowledge with a particular emphasis on explaining the link between kidney disease and hypertension. Patients also wanted more information about medication, diet and other ways of controlling BP. Health professionals pointed to the need for patients to understand risks, targets and the importance of taking medications. Patients felt that participating in a group such as the focus group had in itself allowed them to share experiences and provided support and motivation. They also cited the usefulness of having an experienced health professional as a key contact with whom they could build a relationship and from whom they could obtain ongoing positive support. These key findings and evidence were used to structure a written curriculum that would form the basis of the educational intervention.

The written curriculum was developed to guide the facilitator and to ensure consistency of delivery between education sessions, and a resource folder was created to help participants consolidate their knowledge and improve their self-management skills. The CHEERS curriculum involved the following modules: Blood Pressure and Me; Fact-Finding; How to Control Your BP; Setting, Achieving and Maintaining Goals; and Summary and Take Home Message. The modules were based on social cognitive theory⁶ and incorporated a knowledge element to give patients the necessary information that they needed to know how to effectively self-manage their BP, and a psychological element that involved teaching and encouraging skills, such as goal setting, that were likely to improve the confidence and motivation needed for effective self-management. More information on the CHEERS intervention is available as an online supplementary file. Social cognitive theory⁶ was identified as being particularly relevant and inclusive in terms of meeting the needs of the project that involved self-management education to change health behaviour.

The intervention was delivered in a group format (two to six participants) in a single session lasting 2.5 h. Each participant was scheduled to take part in a session within 3 months of randomisation. They were allowed to bring a friend/relative for support. Eight groups were facilitated by the study nurse who had had previous experience of offering lifestyle advice to patients and who had been observed in a pilot run of the CHEERS education session by two independent nurses to ensure effective

facilitation and engagement of participants in line with the curriculum. All sessions took place in an education centre located at the hospital. This location was chosen as it offered excellent facilities for teaching and a pleasant environment away from the main hospital where participants attended their clinic reviews. Following the education session, all patients were offered access to further support from the study nurse, and reminder letters were sent out 6 months later detailing the goals that each participant has identified in the education session. The additional support was included based on a key finding from the focus groups so that the participants had access (if needed) to a key contact who could offer positive ongoing verbal support and advice via the telephone. If participants failed to attend a session, they received a telephone reminder; if they failed to attend for a second time, no further contact was made.

The different components of the CHEERS educational intervention and the evidence base^{6–8} for their inclusion are listed in [table 1](#).

Feasibility outcomes

Recruitment

The following data were recorded to track recruitment rates and to evaluate the recruitment process:

- ▶ The number of patients approached at clinic following screening.
- ▶ The number of patients consented and randomised.
- ▶ The number of patients approached but not suitable for inclusion in the study.
- ▶ The reasons cited by eligible patients for not wanting to take part in the study.
- ▶ Basic demographic data (age, sex and ethnicity) for recruited versus non-recruited patients.

Retention

The following data were collected to monitor and assess the retention of patients in the control and intervention groups:

- ▶ The number of intervention group patients who failed to attend the education session after agreeing to take part in the study.
- ▶ Demographic (age, sex, ethnicity) and self-efficacy (an individual's confidence in their ability to self-manage their health condition) data for patients not attending the education session versus patients who attended.

All demographic data were collected using the routine patient information entered on our computer-based clinical system (PROTON). Self-efficacy was evaluated at recruitment using the validated Self-Efficacy for Managing Chronic Disease 6-Item Questionnaire.⁹ This is a self-administered scale that covers several domains that are common across many chronic diseases: symptom control, role function, emotional functioning and communicating with physicians.

Table 1 Components and evidence for the CHEERS educational intervention

| Component | Evidence |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| A leaflet on BP control was sent to participants prior to the educational intervention to prepare them for a group discussion. | Preparatory information has been used in a previous successful group education intervention (involving one session) for predialysis patients. ⁷ |
| A single group educational session (lasting 2.5 h) involving facilitated informal discussion, problem-solving activities and sharing of experiences to work through modules that would equip the participants with the necessary knowledge to be able to self-manage their BP. In addition, participants were introduced to the importance of goal setting as an effective self-management skill and were asked to complete an action plan setting out short-term goals. | The intervention used the principles of social cognitive theory ⁶ as a theoretical framework that aimed to engage and empower patients by increasing self-efficacy (a patient's confidence in their own ability to self-manage their health condition) by giving patients the necessary knowledge and skills. |
| Participants were asked to write their goals in a self-addressed letter that was sent to them at 6 months as a reminder. They were also given access to support and advice from the study nurse via telephone or email. | Maintenance of behavioural change is paramount. Reminder letters have been shown to be effective in helping patients maintain positive health behaviours, and additional telephone support has been shown to maintain behavioural change in predialysis patient. ⁸ Support is essential to help overcome any barriers or obstacles to behavioural change. The support was offered rather than enforced to fit with the philosophy of empowerment. |

BP, blood pressure.

Patient satisfaction

Patient satisfaction with the education session was assessed using an evaluation form (figure 1). All participants completing the education session were asked to complete the evaluation form to provide feedback on the delivery and content of the intervention. The form was developed to get feedback on the different components of the CHEERS intervention such as the venue, the educator and length of session, which are all possible recognised influences on the effectiveness of the intervention. A simple 'Yes', 'No' and 'Not Sure' format was used to encourage the participants to answer all the questions and to provide a basic overview of how satisfied patients were with the intervention. In addition, for each question, participants were asked for any comments to provide a more detailed assessment of patient satisfaction. Forms were completed anonymously so that patients would be more likely to give honest feedback.

Patient access of additional support

The number of patients accessing the additional support offered was also recorded to ascertain whether this was an effective strategy.

Randomisation

Recruited patients were randomly allocated to each of the study groups on a 1:1 basis in blocks of six to ensure similarity of numbers in each group. Sealed opaque envelopes were used to ensure allocation concealment until after recruitment. These were prepared by an independent researcher not directly involved in the RCT using a computer-generated randomisation sequence to allocate patients to one of the two study groups.

Blinding

The study was an open unblinded trial. As active recipients of the intervention, participants could not be unaware of whether or not they were offered education. For practical reasons, the evaluator was also not blinded to group allocation as they delivered the education sessions and also collected and entered data on to the database. To help avoid observer bias, the self-efficacy questionnaire and the evaluation form for the educational intervention were self-administered.

Data analysis

Descriptive statistics were generated for recruitment and retention rates and to assess patient acceptability of the educational intervention. All statistical analyses were performed using SPSS (V.16). χ^2 Tests and independent t tests were used to determine whether any significant differences existed between recruited and non-recruited patients for categorical and continuous variables, respectively. These tests were also used to compare the non-attendees at the education session with the participants who attended. A p value of <0.05 was used to determine whether differences were significant and effect sizes with 95% CIs were calculated.

RESULTS

Recruitment and retention

Patient recruitment and retention are shown in figure 2. A total of 267 patients were approached to take part in the study. Eighty-one people (30%) were recruited from July 2006 through July 2007 and were randomly assigned to either the intervention group (n=40) or the control group (n=41). The main reasons cited for non-participation were lack of interest in a patient

Your evaluation

To help us continually improve and develop the C.H.E.E.R.S educational session, we are interested in getting your feedback. Please take a few minutes to answer the following questions: -

- Please tick
- Did you enjoy the session? Yes No Not sure
Any comments:
 - Have you found the session useful? Yes No Not sure
Any comments:
 - Was the session long enough? Yes No Not sure
Any comments:
 - Did you like the venue? Yes No Not sure
Any comments:
 - Did you think the teacher was good? Yes No Not sure
Any comments:
 - Was the size of the group ok? Yes No Not sure
Any comments:
 - Did you feel comfortable? Yes No Not sure
Any comments:
 - Did you enjoy the group tasks? Yes No Not sure
Any comments:
 - Was information well presented? Yes No Not sure
Any comments:
 - Did you understand all information? Yes No Not sure
Any comments:
 - Finally, can we improve the session? Yes No Not sure
Any comments:

Thank-you!

Figure 1 Evaluation form to assess patient satisfaction with educational session.

education session for BP control (44% of those who declined) and the time commitment required to participate (48%). For those approached who did not meet the inclusion criteria (9%), an inability to converse in English was the main reason for exclusion. A comparison of the demographic data (table 2) for recruited patients versus non-recruited patients revealed that there were significantly more men in the recruited population ($p=0.048$; $OR=0.796$, 95% CI 0.642 to 0.986). However, there were no significant differences for age or ethnicity.

Overall, 37.5% of the participants randomised to the intervention group did not attend the education session (figure 2). When compared on the selected variables (table 3), those participants who did not attend were significantly more likely to be older ($p=0.039$; mean difference= $7.85 (\pm 3.67)$, 95% CI 0.428 to 15.278) and have lower levels of self-efficacy ($p=0.034$; mean difference= $-1.8 (\pm 0.79)$, 95% CI -3.449 to -0.151).

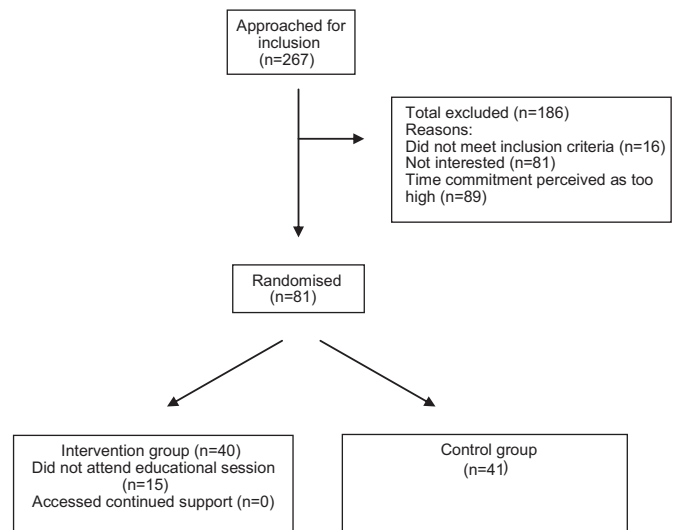


Figure 2 Flow chart of patient recruitment and retention.

Patient satisfaction

The intervention was positively received with 100% of participants rating it as enjoyable. All the participants (100%) also indicated that they felt the education session was useful; the venue was appropriate and they felt comfortable; the facilitator was good and information was well presented and easy to understand. Two patients felt that the session was not long enough, and in the groups where there had been <5 participants, two of the participants would have preferred a bigger group. Very few participants provided additional comments. Two people commented on session length: one wanted more sessions and another felt the one session could be longer. One older participant commented that he had been anxious about attending the group session but really enjoyed it.

Patient access of additional support

None of the participants who attended the education sessions accessed the additional support offered to them (figure 2).

Table 2 Demographics of non-recruited versus recruited patients

| Demographic data | Non-recruited (n=186) | Recruited (n=81) | p Value |
|----------------------|-----------------------|------------------|---------|
| Age (years) | 65.4 (12.2) | 62.8 (11.8) | 0.118 |
| Sex | | | |
| Males | 51.1% (95) | 64.2% (52) | 0.048* |
| Females | 48.9% (91) | 35.8% (29) | |
| Ethnicity | | | |
| White-European | 83.9% (156) | 90.1% (73) | 0.179 |
| South Asian or other | 16.1% (30) | 9.9% (8) | |

Percentages (number of participants) are given for all nominal data with χ^2 tests used for analysis. Continuous data are represented as mean (\pm SD) with independent t tests used for analysis. *Statistical significance indicated by $p<0.05$.

Table 3 Comparison of participants failing to attend the educational session versus those who attended

| Variables | Attendees (n=25) | Non-attendees (n=15) | p Value |
|----------------------|------------------|----------------------|---------|
| Demographics | | | |
| Sex | | | |
| Males | 64.0% (16) | 53.3% (8) | 0.505 |
| Females | 36.0% (9) | 46.7% (7) | |
| Age (years) | 57.68 (14.77) | 65.50 (8.42) | 0.039* |
| Ethnicity | | | |
| White-European | 88.0% (22) | 93.3% (14) | 1.000 |
| South Asian or other | 12.0% (1) | 6.7% (3) | |
| Other | | | |
| Self-efficacy | 7.97 (1.67) | 6.17 (1.85) | 0.034* |

Percentages (number of participants) are given for all nominal data with χ^2 test or Fisher's exact test used for analysis. Continuous data are represented as mean (\pm SD) with independent t tests used for analysis.

*Statistical significance indicated by $p < 0.05$.

DISCUSSION

Although the intervention was well received by participants who attended, our findings suggest that delivering and evaluating an effective structured group educational intervention to promote better BP control in patients with CKD would be challenging in the current context of kidney care. We experienced difficulty with recruitment and retention because patients lacked interest and were reluctant to commit the time to attend a group session, particularly if the patient was older or had a lower self-efficacy level.

Small sample sizes and high dropout rates are recognised problems for the evaluation and delivery of educational interventions in kidney care.² Previous studies have involved multiple education sessions that required a large time commitment from patients.² We had aimed to maximise participation, by keeping time commitment to a minimum with just one session supplemented by telephone support. However, our findings suggest that a group education session in addition to normal clinic visits did not engage the majority of our patients.

The main reasons given by the patients for not wanting to be recruited to the study were a lack of interest and time. Many patients approached for the study demonstrated evidence of confusion; they did not acknowledge that they had a significant problem with their kidneys or BP; therefore, they did not perceive the need for any education. Confusion and negative feelings among patients have been reported in qualitative studies looking at the experiences of people with hypertension¹⁰⁻¹² and diabetes.¹³

We also previously conducted a focus group study in people with CKD, which showed that patient confusion and negative feelings were key issues for BP control.¹⁴ Specifically, lack of basic knowledge appeared to

contribute strongly to confusion and higher levels of confusion appeared to correlate with negative attitudes towards patient empowerment and education. This qualitative study suggested the need for appropriate education and support to increase knowledge and motivation to overcome the confusion and negativity expressed. However, the findings from the current study suggest that if education and support is offered as a patient choice, then many patients are unlikely to take up this option because they are not able to perceive the benefits. Even for those people who did participate in the education session and who had indicated that they had enjoyed the session and found it beneficial, allowing patient choice for the additional continued support following the session resulted in none of these participants contacting the study nurse. Continued support is an essential component of effective behavioural change, but the support offered in the current study failed to be accessed by the participants and as a result there were no significant improvements in BP control or any other cardiovascular risk factors (further details of these results are available from the author). The reason why the additional support was not accessed is not clear, but the participants failed to see the need for it.

Patient confusion in people with CKD is a key factor in the management of BP that needs to be addressed at the earliest opportunity to prevent negative attitudes and to increase interest in empowerment and education. The new NHS Health Checks launched recently by the Department of Health¹⁵ aimed at identifying those people at risk of diseases such as cardiovascular disease, diabetes, stroke and CKD may offer a strong opportunity to address this issue and promote more general awareness about CKD.

In contrast, in diabetes education, researchers have successfully recruited and retained participants in their group education programmes.^{16 17} A culture of patient empowerment and education is well established in diabetes care as part of routine care, evidenced by the fact that people with diabetes appear to be more motivated to take part in educational interventions.

Men were significantly easier to recruit than women. This difference may be due to the fact that many of the women commented that they had family commitments and did not feel that they could spare the additional time for the education session. Time commitment in general was a major reason that people gave for not taking part in the study. This issue is important for designing an effective educational intervention. Either the education has to take place during normal clinic visits and be structured so that it is not seen as an 'optional extra' or a format is required that allows patients to access education at their own convenience (eg, using information technology).

Recruiting patients from ethnic minority backgrounds to take part in research can be difficult.¹⁸ In this study, there were no significance differences found for ethnicity regarding the recruitment and retention of patients.

However, it must be acknowledged that there were relatively low numbers of ethnic minority patients and people without English language skills were excluded.

The participants who failed to attend for the education session were significantly older and had lower levels of self-efficacy when compared to the people who did attend. It could be speculated that the group format for people with CKD was intimidating for older people who may be unfamiliar with this type of education and for those with less confidence as it demands interaction with other patients. In the evaluation, one older participant commented that he had been anxious about attending the group session and it could be surmised that this was a reason why so many people failed to attend. Although we have no direct evidence for this, other reasons for the high dropout rate may have been related to parking and transport issues despite reimbursement of costs.

The current pilot study was established as a robust evaluation of recruitment, retention and patient satisfaction for a definitive trial and employed appropriate randomisation procedures so that the evaluation took place under controlled conditions. A weakness of the study is that the blinding procedures for group allocation post-randomisation were limited due to the open nature of the study and because of practical reasons, which meant that the evaluator was aware of group allocation as they were also involved in data collection and entry and were responsible for delivering the education session. The evaluation form for assessing patient satisfaction was also limited as we received very few additional comments to allow a more detailed assessment. On reflection, the form contained too many closed questions, which limited the responses and a number of the questions needed to be reworded so that it was more clear what was being asked. However, as a pilot evaluation of a structured group educational intervention for people with CKD, the current study has highlighted the importance of in-depth evaluations of recruitment and retention in order to increase our understanding of how to engage patients more effectively and design better educational interventions. The current study showed that the structured group intervention in its current format is not effective as we failed to recruit and retain patients and the support that was offered was insufficient for our patients' needs.

The message that emerges from this pilot study is that before effective education can take place, people need to be much more aware of kidney disease as an entity and its implications for health. Time needs to be spent to foster a culture of patient empowerment in people with kidney disease in order to encourage more interest in education. A system is needed whereby education and continued support are an intrinsic part of routine care for people with CKD. This would help to create a culture of education and empowerment that is currently lacking for these patients. This strategy could also promote

the recruitment of people with early kidney disease in clinical research as they would have a greater understanding of their condition.

Measuring self-efficacy levels is an important part of the process for developing an effective educational intervention. Self-efficacy has been shown to be one of the most consistent predictors of successful self-care behaviour and has been incorporated into most health psychology models.¹⁹ Educational interventions will probably work best if education is tailored to take this into account so that additional help and support can be given if required. By identifying those people who lack motivation and confidence, additional help and support could be targeted much more effectively. A possible strategy would be to target resources on training healthcare professionals to use validated questionnaires during clinic consultations to help them to assess levels of self-efficacy more effectively. This could lead to better use of limited resources and potentially improve the effectiveness of educational interventions for people with CKD.

Funding JB received funding from Kidney Research UK (The Edith Murphy Fellowship Programme: TF/EMP/3/04).

Competing interests None.

Ethics approval Ethics approval was provided by the Leicestershire, Northamptonshire and Rutland Research Ethics Committee 2 (06/Q2502/4).

Contributors JB drafted the manuscript with SC, MS, AF and KK providing critical revision. JB developed the design of the educational intervention and resources, recruited patients, coordinated the implementation of the intervention and undertook all the analyses as part of her PhD supervised by SC, MS, KK and AF. SC, MS, KK and AF designed the study and obtained funding. All contributors have approved the final version of the manuscript.

Provenance and peer review Not commissioned; externally peer reviewed.

Data sharing statement Details of the educational intervention curriculum and resource folder plus a complete list of the clinical outcomes from the feasibility study are available from the corresponding author jo.l.byrne@uhl-tr.nhs.uk. Consent was not obtained but the presented data are anonymised and risk of identification is low.

REFERENCES

1. Warsi A, Wang PS, LaValley MP, *et al.* Self-management education programs in chronic disease: a systematic review and methodological critique of the literature. *Arch Intern Med* 2004;164:1641–9.
2. Mason J, Khunti K, Stone M, *et al.* Educational interventions in kidney disease care: a systematic review of randomized trials. *Am J Kidney Dis* 2008;51:933–51.
3. Campbell M, Fitzpatrick R, Haines A, *et al.* Framework for design and evaluation of complex interventions to improve health. *BMJ* 2000;321:694–6.
4. Craig P, Dieppe P, Macintyre S, *et al.* Developing and evaluating complex interventions: the new Medical Research Council guidance. *BMJ* 2008;337:a1655.
5. Joint Speciality Committee on Renal Medicine. *Chronic Kidney Disease in Adults: UK Guidelines for Identification, Management and Referral (full guideline)*. London: RCP, 2006.
6. Bandura A. Health promotion from the perspective of social cognitive theory. In: Norman P, Abraham C, Conner M, eds. *Understanding and Changing Health Behaviour: From Health Beliefs to Self-regulation*. Amsterdam: Harwood Academic Publishers, 2000:299–399.
7. Manns BJ, Taub K, Vanderstraeten C, *et al.* The impact of education on chronic kidney disease patients' plans to initiate dialysis with self-care dialysis: a randomized trial. *Kidney Int* 2005;68:1777–83.
8. Devins GM, Mendelssohn DC, Barre PE, *et al.* Predialysis psychoeducational intervention and coping styles influence time to

- dialysis in chronic kidney disease. *Am J Kidney Dis* 2003;42:693–703.
9. Lorig KR, Sobel DS, Ritter PL, *et al*. Effect of a self-management program on patients with chronic disease. *Eff Clin Pract* 2001;4:256–62.
 10. Gascon JJ, Sanchez-Ortuno M, Llor B, *et al*; Treatment Compliance in Hypertension Study Group. Why hypertensive patients do not comply with the treatment: results from a qualitative study. *Fam Pract* 2004;21:125–30.
 11. Rickerby J, Woodward J. Patients' experiences and opinions of home blood pressure measurement. *J Hum Hypertens* 2003;17:495–503.
 12. Sims J. What influences a patient's desire to participate in the management of their hypertension? *Patient Educ Couns* 1999;38:185–94.
 13. Stewart J, Brown K, Kendrick D, *et al*; Nottingham Diabetes and Blood Pressure Study Group. Understanding of blood pressure by people with type 2 diabetes: a primary care focus group study. *Br J Gen Pract* 2005;55:298–304.
 14. Mason J, Stone M, Khunti K, *et al*. Educational needs for blood pressure control in chronic kidney disease. *J Ren Care* 2007;33:134–8.
 15. NHS Health Check Programme. Putting Prevention First – NHS Health Check Vascular Risk Assessment Management Best Practice Guidance. London: Department of Health, 2009.
 16. Davies MJ, Heller S, Skinner TC, *et al*; Diabetes Education and Self Management for Ongoing and Newly Diagnosed Collaborative. Effectiveness of the diabetes education and self management for ongoing and newly diagnosed (DESMOND) programme for people with newly diagnosed type 2 diabetes: cluster randomised controlled trial. *BMJ* 2008;336:491–5.
 17. Deakin TA, Cade JE, Williams R, *et al*. Structured patient education: the diabetes X-PERT Programme makes a difference. *Diabet Med* 2006;23:944–54.
 18. Hussain-Gambles M, Atkin K, Leese B. Why ethnic minority groups are under-represented in clinical trials: a review of the literature. *Health Soc Care Community* 2004;12:382–8.
 19. Norman P, Conner M. The role of social cognition models in predicting health behaviours: future directions. In: Conner M, ed, *Predicting Health Behaviour*. Buckingham: Open University Press, 1996:197–225.