

# 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

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## 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.<sup>1</sup> 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 review<sup>2</sup> 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.<sup>3 4</sup> 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 m<sup>2</sup>) 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.<sup>5</sup> 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 theory<sup>6</sup> 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 theory<sup>6</sup> 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<sup>6–8</sup> 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.<sup>9</sup> 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. <sup>7</sup>
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 <sup>6</sup> 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. <sup>8</sup> 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).  $\chi^2$  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: -

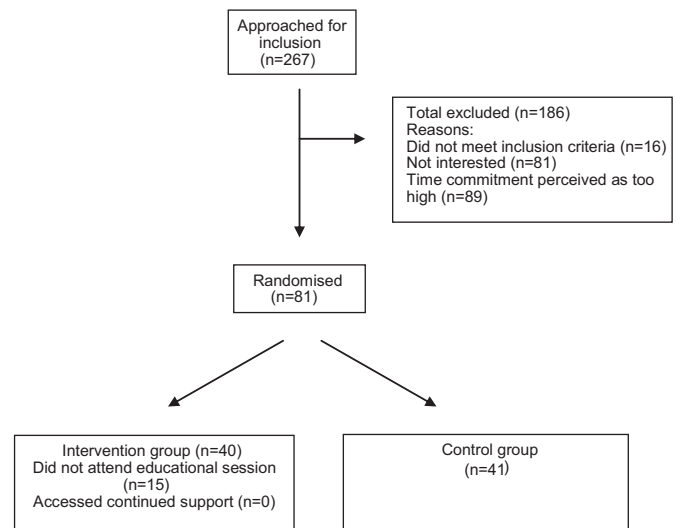
- Please tick
- Did you enjoy the session? Yes ☐ No ☐ Not sure ☐  
Any comments:
  - Have you found the session useful? Yes ☐ No ☐ Not sure ☐  
Any comments:
  - Was the session long enough? Yes ☐ No ☐ Not sure ☐  
Any comments:
  - Did you like the venue? Yes ☐ No ☐ Not sure ☐  
Any comments:
  - Did 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	16.1% (30)	9.9% (8)	
or other			

Percentages (number of participants) are given for all nominal data with  $\chi^2$  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  $\chi^2$  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.<sup>2</sup> Previous studies have involved multiple education sessions that required a large time commitment from patients.<sup>2</sup> 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 hypertension<sup>10–12</sup> and diabetes.<sup>13</sup>

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.<sup>14</sup> 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 Health<sup>15</sup> 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.<sup>16 17</sup> 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.<sup>18</sup> 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.<sup>19</sup> 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.

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**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.

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**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.

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Supplementary file:

The CHEERS Intervention Curriculum

## Section 1: Introductions, housekeeping and aims

### Participants' learning objectives

- To get to know the facilitators and the rest of the group.
- To understand general housekeeping issues (i.e. toilets, fire exits etc.).
- To know when breaks and refreshments will be.
- To realise that the session will be conducted in a relaxed and friendly manner and questions will be encouraged.
- To understand that everyone will be treated with respect and will be listened to.
- To understand the overall aims of the session and how these will be achieved.

### Facilitator's role

- To record attendance on arrival.
- To welcome all patients and relatives.
- To introduce themselves and any observers and their roles.
- To ask all participants to introduce themselves to the group.
- To behave in a friendly and relaxed manner.
- To describe all housekeeping issues.
- To give times for breaks and refreshments.
- To treat everyone with respect and to listen to their problems.
- To explain the overall aims and plan of the session and what is hoped to be achieved.
- To encourage participants to ask questions at any time if they are unclear about something.

### Teaching plan

The main aim is to set out clear expectations for all and to create an informal and relaxed feel that will encourage interaction.

## Suggested script for 'introductions, housekeeping and aims'

- Welcome everybody and make introductions and any explanations brief and deliver in a 'chatty' manner sitting down.
- Outline the goals:
  - To understand the experiences of the group with controlling their BP.
  - To have a fact finding session about BP.
  - To consider ways of controlling BP.
  - To encourage effective goal setting.

## Section 2: Blood pressure and me

### Participants' learning objectives

- To understand the different experiences and perceptions of BP control for people with kidney problems as held by the group.
- To interact with the group and educators to find out what the key issues are for the group.

### Facilitator's role

- To allow the group the opportunity to tell their experiences and perceptions of BP control.
- To highlight the key issues surrounding the groups understanding and perceptions of BP control.

### Teaching plan

The aim is to explore the knowledge base of the participants and to get an idea about their self-efficacy and willingness to change their health habits.

### Suggested script for 'Blood pressure and me'

- Ask participants to consider the following questions and to compare their experience with another member of the group before reporting back to the rest of the group:  
-How did you find out that you had high BP?  
-How did you feel?  
-What did you do?  
-What would you like to learn today?
- Compile a list of answers on a flipchart to highlight the key issues to visually summarise the information for the group.
- Thank everyone to reinforce the importance of his/her contribution.

## Section 3: Fact-finding

### Participants' learning objectives

- To understand what BP is and how it works.
- To understand the link between high BP and kidney disease.
- To understand why we need to control BP.
- To understand why we measure BP.
- To understand how we measure BP.
- To understand what BP targets are.
- To understand how we can lower BP.

### Facilitator's Role

- To inform and give knowledge about BP and kidney disease to help empower patients.
- To explain difficult concepts in ways which are easy to understand and to encourage participants to think about their BP.
- To answer any queries or issues which were raised by participants in the previous section.

### Teaching Plan

The aim is to give the group the information that they need to know about BP. Diagrams and simple language are used to explain difficult concepts. Reflective questioning is used to encourage engaged thinking and prompt answers. Learning is also reinforced with the use of a practical demonstration and a problem-solving activity.

### Suggested script for 'Fact-finding'

- Ask: *What is BP and how does it work?*  
*Answer: Your BP is the pressure on the walls of your arteries (the tubes that carry the blood away from your heart and around the body).*
- Ask: *What happens as people get older?*  
*Answer: As people get older and as arteries furr up, they become stiffer, and the pressure increases.*
- Ask: *What effect does high BP have on the arteries?*  
*Answer: High BP (also known as hypertension) means more stress on the artery wall, which can lead to more damage and furring. As a result, our blood vessels become very narrow or even blocked, which can slow or stop blood getting round the body.*
- Draw a big tube on a flip chart and show how high BP and furring work to narrow the blood vessel.
- Ask: *Why do we need to control our BP?*
- Answer: *We need to control our BP to prevent our blood vessels from getting furred up and damaged so that blood can get round the body and take oxygen to our vital organs. These are parts of our body such as the brain, heart and kidneys.*
- Ask: *Does anyone know what happens if not enough blood gets to our vital organs such as the brain, heart and kidneys?*  
*Answer: We could have a heart attack, stroke or cause kidney failure and this is why it is so important for us to control our BP.*
- Then proceed to look at the kidneys in more detail and how high BP can cause kidney failure.
- Ask: *What do our kidneys do?*

*Answer: They act like a sieve to filter out toxins that we don't need from the blood and also help to regulate the amounts of fluid, minerals and vitamins in bodies.*

- Draw a simple kidney on the flip chart with a tube going in and a tube going out. In the 'going in' tube draw red circles to represent blood and green circles to represent toxins and excess fluid etc. Proceed to draw a sieve under the kidney to demonstrate the filter process and then just draw red circles (minus the green circles) in the 'going out' tube to represent the filtered blood.

- Ask: What happens to the toxins and excess amounts of fluid etc that are filtered from the blood?

*Answer: They go through the kidneys into the bladder and then into our urine.*

- Demonstrate this using the diagram that you drew.

- Ask: What happens to this process if we have high BP?

*Answer: Due to the 'furring' we have already discussed, high BP restricts the blood flow and oxygen getting to the kidneys and they are not able to function properly. Also, the high pressure over time causes the kidneys (the 'sieves') to get bigger holes that gradually destroy the 'sieves' and prevent the filter process. As a result, the kidneys are no longer effective at removing toxins and excess amounts of fluid, vitamins and minerals from our bodies and we need a dialysis machine to do the job for us.*

- Ask: We have learnt how high BP damages our kidneys; do you think that kidney damage can cause high BP?

*Answer: Yes. The filter system helps to keep our BP under control by regulating the amount of fluid in our blood. If this filter system is damaged in any way then this will cause our BP to rise.*

- Ask: Is high BP common in people with kidney disease?

*Answer: Yes, it is very common and it often develops when the kidney damage is very mild so many people may not even be aware of any kidney problems when they are diagnosed with high BP.*

- Explain briefly the CKD stages (1-5) so that the participants understand the difference between mild and severe kidney damage.

- Ask: How do we know if we have got high BP?

*Answer: High BP only rarely gives rise to symptoms when very high. The only accurate way to tell if you have high BP is to measure it.*

- Ask: How do we measure BP?

*Answer: We use a sphygmomanometer to measure BP.*

- Show examples of a manual and electronic sphygmomanometers.

- Ask: Can anyone show us how we write BP numbers?

*Answer: We write BP numbers like this '140/80'*

- Ask: What do we call the top and bottom numbers?

*Answer: The top number is called your 'systolic' BP and the bottom number the 'diastolic'.*

- Write both words on flip chart to reinforce this point

- Ask: What is the difference between the systolic and diastolic?

*Answer: The systolic is the high pressure as the heart is pumping and the diastolic the lower pressure as it relaxes.*

- Use a volunteer to demonstrate that when the cuff gets really tight on the arm this is to measure the top number (the systolic pressure) and when the cuff is deflating this is measuring the bottom number (the diastolic pressure).

- Ask: How many times should we do this at one visit and why?

*Answer: It is good practice to take the BP more than one time to check that the measurement is correct and that we are getting similar results for each measurement. Also, it is important that you are relaxed when you have your BP measured. Sometimes, when people are not relaxed, their BP can be higher than it really is. This is known as the 'white coat effect'.*

- Ask: How does your doctor know what is happening with your BP?

*Answer: It is important that the medical professionals know what is happening with your BP and this is why you will have your blood pressure taken on many of your visits to your local health centre or hospital. Sometimes, we may even send you home with cuff fitted to*



*your arm that will record your BP over 24 hours so that we can get a clear picture of what is happening.*

- Ask: Why is self-monitoring useful?

*Answer: Self-monitoring and writing down your BP on a regular basis will help your doctor develop a clearer picture of your BP patterns that is not just based on one-off results.*

- Ask: What are BP targets and what do they need to be?

*Answer: Targets are guidelines set by governing bodies based on available evidence. The target recommended for people with kidney disease is 130/80. Reaching this target is considered to reduce the risks of heart and kidney disease. We are much fussier for people with kidney disease because they have a higher risk than the general population. Sometimes, we may even aim for an even lower BP (125/75), if there are other problems that increase that risk such as protein in the urine.*

- Write a few blood pressures on the flip chart, you ask which is on target and which is too high to test the participants' understanding.

- Ask: How can we lower our BP?

*Answer: We can reduce our BP by:*

- Taking our BP drugs
- Avoiding being overweight
- Keeping our alcohol intake down
- Reducing our salt intake
- Exercising regularly
- Stopping smoking

- Write these on a flip chart for use in the next session

Break for coffee

#### Section 4: How to control your BP

##### Participants' Learning Objectives

- To learn of practical ways to reduce BP.

- To understand current recommendations
- To understand that everyone is different things will work for different people.

##### Facilitator's Role

- To explore practical ways of reducing current recommendations.
- To discuss what is meant by the recommendations.
- To help the group understand that what one person will not necessarily work for another person.

##### Teaching Plan

The main aim is to look at different ways of BP that the participants can adopt. The list compiled from the previous used as a prompt to explore the issues in more depth. This is done through group discussion and problem solving activities to help stimulate engaged thinking.

##### Suggested script for 'How to BP'

- Ask: Why does your doctor give you BP?

*Answer: Large research trials show that tablets are effective at controlling BP.*

- Ask: Does everyone take the same BP?

*Answer: Different tablets work for people and different combinations and numbers of tablets required. The average number of tablets in renal patients to get levels is three.*

- Ask participants to form two groups of the different types of blood tablets that they take.

- Ask the groups to report back after 10 minutes of discussion and write down answers on the flip chart – ramipril, nifedipine, atenolol).

- Circle the ends of any generic drug names the same

- Ask: Why do these drugs end in the same?

*wine, a pub measure of spirits or half a pint of ordinary strength lager or beer.*

- Ask: How do you reduce your alcohol intake

*Answer: Only drink alcohol in small amounts and avoid binge drinking.*

- Ask: What are the recommendations for physical activity?

*Answer: Aim to build up to 30 minutes of activity at least five times per week. Any activity you do should leave you slightly out of breath but you should still be able to talk.*

- How can you increase your physical activity?

*Answer: Being active doesn't have to mean jogging or aerobics. Walking on a regular basis is a suitable activity. Other good activities are cycling, dancing, swimming. The most important thing is to do something that you enjoy as that way you are more likely to stick at it. If you are not very active now, then you do need to take care to begin with and build up your activity levels gradually.*

- Ask: What is the advice about smoking?

*Answer: The advice is to stop smoking*

- How can you give up smoking?

*Answer: Some people can give up by themselves but for many it is extremely difficult to stop smoking. Help is available by contacting your GP or an advice help line (information available in folder).*

- Ask: Why do we have recommendations?

*Answer: Recommendations act as a guide for what we should be aiming for in order to reduce our BP effectively.*

- Ask participants to come up with some practical ideas for helping to reduce weight, cut down on alcohol intake, reduce salt intake, increase exercise and stop smoking.
- Ask the group about their ideas and write these on the flip chart.

- Go through the list and ask each participant which ideas they like to show that different ideas will appeal to different people.

- Ask: Where else can we get useful ideas for making lifestyle changes?

*Answer: Important sources of information include dieticians, nurses, doctors, the Internet, health leaflets. Renal patients should always check with a dietician / doctor if they are going to change their diet. Some foods that are healthy for the general population are not healthy for people with kidney disease.*

- Show the group the 'Really Useful List' in their folders that details contacts and websites for more information on lifestyle change advice.

## Section 5: Setting, achieving and maintaining goals

### Participants' learning objectives

- To understand the importance of goal setting.
- To understand how to set achievable and realistic goals.
- To understand the barriers to achieving goals.
- To understand the importance of social support to achieve and maintain goals.
- To understand how to effectively communicate with the health professionals.
- To create an individualised action plan for controlling BP.

### Facilitator's role

- To explain about goal setting and how to be successful at it.
- To explore what barriers can affect achieving goals.
- To emphasise the importance of social support to achieve and maintain goals.
- To give examples of types of goals.

- To encourage participants to communicate more effectively with health professionals.
- To help each of the participants to create a personal action plan.

### Teaching Plan

The aim is to stimulate the group to think about how they can actually change their lifestyles and habits and use tools (self-monitoring and action plans) for doing so. Effective goal setting techniques and barriers to goal setting is explored through group discussion and examples. The group will also consider how they can maintain their goals through social support, effective communication with health professionals and by using a reminder letter.

#### Suggested script for 'Setting, achieving and maintaining goals

- Ask: Why do we need to set goals?  
*Answer: Goal setting is an important part of changing our behaviour. By setting goals, we are able to motivate ourselves and they give us something to aim for.*
- Ask: Can you give me some examples of when we use goals?  
*Answer: We use goals in our jobs, resolutions, household tasks, travel etc.*
- Write answers on flip chart.
- Ask: What stops us from achieving our goals?  
*Answer: There are many barriers to achieving goals – psychological, social, economical and physical factors all have an influence*
- Write down any barriers identified by the group?
- Ask: What makes a good goal?

*Answer: A good goal has to be relevant, understandable, measurable, behavioural and achievable.*

- Write down the acronym RUMBA on the flip chart to help the group remember the above principles of effective goal setting.
- Ask: If for example, I want to reduce my BP because it is too high. Do you think that I will be able to make all the changes that we discussed earlier straight away?

*Answer: Too many changes at once will not be achievable for many people due to the pressures of daily life.*

- Ask: How can I change my goal to make it more effective?  
*Answer: The overall goal needs to be broken down into much smaller manageable steps that are much more relevant, understandable and achievable.*

- Ask: Can you give me some ideas of changes that I could make to start me on my way?

*Answer: Ideas could include walking to work three times per week instead of taking the bus, having no extra salt on my food, only having two glasses of wine on a Friday night etc.*

- Write these ideas on the flip chart
- Ask: I have picked three changes that I want to make. Would you pick the same changes?  
*Answer: Different people will need to make different changes so that they are relevant to them.*

- Ask: In the long-term what do I want these changes to become?  
*Answer: In the long-term, these changes will hopefully be part of a daily routine like making the bed or doing the shopping.*

- Ask: Is it effective to evaluate our success in terms of long-term behaviour?



*Answer: We get very set in our ways and we need to remember that changing our behaviour after doing something different for many years can be very difficult. So, to start off with, it is probably best to set a short-term goal that is done over a week.*

- Ask: If after one week I have achieved my goal, what do I need to do next?

*Answer: After the first week you can set a new goal to continue for another week and so on until goal setting becomes part of your behaviour. What is important is that you are always in control. If you build the changes up slowly, you will probably find that achieving your goals will become much easier and more enjoyable.*

- Ask: If I am finding something hard what should I do?

*Answer: If a goal is too hard to achieve it should be reconsidered and reshaped to make it more achievable (e.g. break down 20 minutes of exercise into two 10 minute sessions).*

- Ask: How can we keep motivated to keep achieving our goals?

*Answer: Ideas could include self-motivation, group support, family support, access to information, joining fitness clubs, smoking cessation clinics etc.*

- Write down any ideas on the flip chart

- Point out the list of support groups, clubs etc in the manual that people could access.

- Ask: Is anyone a member of a club or group already that they could recommend to the others?

- Ask: What role does fear play in all this?

*Answer: Fear often stops us from doing things. Remember that we all have our anxieties and worries. The first step is a hard one but once we take this step then reaching our goals becomes easier.*

- Ask: Do you think that knowing more about your health will have an effect on motivation?

*Answer: If you take an interest in your health and start paying attention to your blood pressure figures and writing down results when you go to the doctor, you will hopefully find that this too will help your motivation and will get you to make lifestyle changes.*

- Point out the section in the folders for recording BP and suggest that this monitoring sheet can be used for every health visit.

- Ask: Is this information useful for your doctors too?

*Answer: By doing this, you will be able to track your own health and this will be helpful to both you and your doctor. By asking them for your results and by writing them down, you are also showing them that you are interested in your health and want to know more.*

- Ask: Who is in control of your BP – you or the doctor?

*Answer: The doctor wants to keep your BP well controlled and so do you. You have to work together to achieve this.*

- Ask: How can you communicate more effectively with health professionals to find out what you need to know?

*Answer: You can ask them to explain something to you in simple terms. We often use words that people don't understand. If patients are not happy with their tablets or some other aspect of their care they need to say so. If a patient wants advice then they need to ask for it. As health professionals, we try to meet patients' needs but we don't always know what patients want and sometimes we need a bit of help from them. Writing questions down is a useful way of remembering what you want to ask.*

- Write a list on the flip chart of the ways in which the participants could improve their communication with their health professionals.
- Ask each of the participants to create an action plan using the section in their folders to set out the goals that they would like to make using the information that they have learnt.
- Give help if required
- Ask the group to write these goals in a self-addressed letter and tell them that this will be sent to them in a few months time as a reminder.



### 1.1.1 Section 6: Summary and take home message

#### Participants' learning objectives

- To have a clear understanding of the importance of controlling BP.
- To feel empowered and able to make lifestyle changes to control their BP.

#### Facilitator's role

- To summarise all the main aims to help consolidate knowledge.
- To help the group feel empowered and to give them the confidence that they need to make lifestyle changes.
- To offer further support if required.

#### Teaching plan

In this final session, the aim is to do a brief summary of all the main learning outcomes to help get the message across that the control of BP is very important for health. The group is then encouraged to take control and to use the skills that they have learnt.

#### Suggested script for 'Summary and take home message'

- Ask: What have we learnt today?

*Answer: We have learnt all about BP and why it is so important to control it to prevent heart attacks, strokes and kidney disease. We have looked at the targets that we need to achieve and the changes that we can make to do this. Finally, we have talked about how to set realistic goals for making lifestyle changes and how we can maintain these goals in the future.*

- Ask: Does anyone have any further questions?

- Tell the group that if they have any more questions or want more advice they can feel free to contact yourself. The number is in the folder and you are happy to give advice and support over the phone.
- Ask the group to fill out an evaluation form.
- Take home message: I'd like to thank you all for coming today and hope that you have found the session to be of use. All of you now have your folders so that you can record your results and goals and to help you keep in control of your BP and your health. You have set some goals today and now you need to leave here and achieve these goals. You all have the ability to make changes, so make the choice and be in control!
- Write BE IN CONTROL in bigger letters on the flip chart to emphasise this take home message.