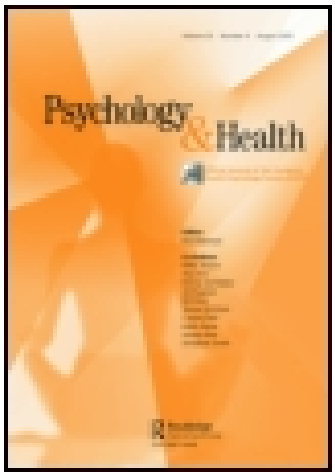

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Evidence of improved fluid management in patients receiving haemodialysis following a self-affirmation theory based intervention: a randomised controlled trial.

Vari Wileman[ab], Joseph Chilcot[b], Christopher J. Armitage[c], Ken Farrington[d], David M. Wellsted[a], Sam Norton[b], Andrew Davenport[e], Gail Franklin[d], Maria Da Silva Gane[d], Robert Horne[f] & Mike Almond[g]

[a] School of Psychology, University of Hertfordshire

[b] Institute of Psychiatry, King's College London, UK

[c] University of Manchester, UK

[d] Lister Hospital, Stevenage UK

[e] Royal Free, London, UK

[f] UCL School of Pharmacy

[g] Southend University Hospital, UK

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Title

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Corresponding author

Vari Wileman PhD[1,2]
University of Hertfordshire, Room 1F424, Health Research Building, College Lane, Hatfield AL10 9AB. Tel: 01707 284000, v.a.wileman@herts.ac.uk

Co-authors

Joseph Chilcot PhD CPsychol[2]
Health Psychology Section, Department of Psychology, Institute of Psychiatry
King's College London, 5th Floor, Bermondsey Wing, Guy's Hospital, London SE1 9RT
Tel: 020 7188 2597, joseph.chilcot@kcl.ac.uk

Christopher J. Armitage PhD CPsychol[3]
Manchester Centre for Health Psychology, School of Psychological Sciences,
Manchester Academic Health Science Centre, University of Manchester, Coupland Street
Oxford Road, Manchester, M13 9PL. Tel: 0161 275 2556. chris.armitage@manchester.ac.uk

Ken Farrington MD FRCP [4]
East & North Herts NHS Trust, Renal Unit Lister Hospital, Coreys Mill Lane, Stevenage,
Hertfordshire SG1 4AB Tel: 01438 314333, ken.farrington@nhs.net

David M. Wellsted PhD [1]
University of Hertfordshire, Room 1F424, Health Research Building, College Lane, Hatfield AL10 9AB. Tel: 01707 284000, d.m.wellsted@herts.ac.uk

Sam Norton PhD [2]
Health Psychology Section, Department of Psychology, Institute of Psychiatry
King's College London, 5th Floor, Bermondsey Wing, Guy's Hospital, London SE1 9RT
Tel: 020 7188 2597, sam.norton@kcl.ac.uk

Andrew Davenport MD FRCP [5]
UCL Centre for Nephrology, Royal Free Hospital, Pond Street, London NW3 2QG.
Tel: 020 7794 0500, andrew.davenport@nhs.net

Gail Franklin BSc[4]
East & North Herts NHS Trust, Renal Unit Lister Hospital, Coreys Mill Lane, Stevenage, Hertfordshire SG1 4AB Tel: 01438 314333, gail.franklin@nhs.net

Maria Da Silva Gane MSc [4]
East & North Herts NHS Trust, Renal Unit Lister Hospital, Coreys Mill Lane, Stevenage, Hertfordshire SG1 4AB Tel: 01438 314333, maria.dasilvagane@nhs.net

Robert Horne PhD[6]
School of Pharmacy, UCL, Mezzanine Floor, BMA House,Tavistock Square, London WC1H 9JP
Tel: 0207 874 1293, rob.horne@pharmacy.ac.uk

Mike Almond DM FRCP [7]
Southend University Hospital NHS Foundation Trust, Prittlewell Chase, Westcliff-on-Sea, Essex SS0 0RY. Tel: 01702 435555, mike.almond@southend.nhs.uk

Affiliations in brief

[1]School of Psychology, University of Hertfordshire
[2]Institute of Psychiatry, King's College London, UK
[3]University of Manchester, UK
[4]Lister Hospital, Stevenage UK
[5]Royal Free, London, UK
[6]UCL School of Pharmacy
[7]Southend University Hospital, UK

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Manuscript title page

Evidence of improved fluid management in patients receiving haemodialysis following a self-affirmation theory based intervention: a randomised controlled trial.

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Abstract

Objective Haemodialysis patients are at risk of serious health complications, yet treatment non-adherence remains high. Warnings about health-risks associated with non-adherence may trigger defensive reactions. We studied whether an intervention based on self-affirmation theory reduced resistance to health-risk information and improved fluid treatment adherence.

Design In a cluster randomised controlled trial, ninety-one patients either self-affirmed or completed a matched-control task before reading about the health-risks associated with inadequate fluid control.

Outcome measures Patients' perceptions of the health-risk information, intention and self-efficacy to control fluid, were assessed immediately after presentation of health-risk information. Interdialytic-weight-gain (IDWG), excess fluid removed during hemodialysis, is a clinical measure of fluid treatment adherence. IDWG data were collected up to 12 months post intervention.

Results Self-affirmed patients had significantly reduced IDWG levels over 12 months. However, contrary to predictions derived from self-affirmation theory, self-affirmed participants and controls did not differ in their evaluation of the health-risk information, intention to control fluid or self-efficacy.

Conclusion A low-cost, high-reach health intervention based on self-affirmation theory was shown to reduce IDWG over a 12-month period but the mechanism by which this apparent behaviour change occurred is uncertain. Further work is still required to identify mediators of the observed effects.

Keywords

Self-affirmation
Behaviour change
Dialysis
Adherence
Interdialytic-weight-gain
Fluid control

Introduction

Patients with end stage kidney disease (ESKD) are not able to excrete sufficient or in some cases any urine. Dialysis removes excess fluid but there are limits to how much fluid can be safely removed during a single dialysis session. ESKD patients receiving haemodialysis are required to restrict their fluid and salt intake as inadequate fluid control is associated with poor short term (e.g. hypertension, painful cramps during dialysis and extended dialysis sessions) and long term health outcomes (e.g. pulmonary oedema, cardiovascular risk and increased

mortality) see (Davenport, 2006; Denhaerynck et al., 2007). It is recommended that patients drink no more than 500mls of liquid plus an amount equivalent to estimated urine output, per day. To prevent increased fluid gains, patients should be attending for dialysis sessions with approximately 1-2 kilograms of interdialytic weight gain (IDWG). The weight gained between dialysis sessions (IDWG) indicates the amount of the excess fluid that needs to be removed in the treatment session, with greater weight gains indicating problematic fluid control. Although related to body size and residual renal function, IDWG serves to be the most reliable objective marker of fluid adherence. Studies of fluid adherence indicate that, perhaps not surprisingly, many patients find this particularly challenging to manage and often commence dialysis with significantly higher IDWGs than clinically desired. Estimates of fluid treatment control non-adherence vary widely (Clark, Farrington, & Chilcot, 2014), between 10-60% when using IDWG as a proxy measure of adherence, and, 30-74% based on patient self-report (Denhaerynck et al., 2007).

Patients are regularly informed and reminded about their recommended treatment in routine care, particularly fluid control, since patients are weighed before and after every dialysis session. However, merely educating patients about the risk of poor treatment control is not always sufficient to change behaviour (Barnett, Li Yoong, Pinikahana, & Si-Yen, 2008; Haynes, 1999). For patients who consistently fail to keep within recommended fluid levels, the receipt of regular feedback that their behaviour is putting their health at risk, is potentially threatening. Such perceptions of threat may lead to defensive responses (Cohen & Sherman, 2014). Self-affirmation theory (Steele, 1988) predicts that people are likely to ignore or reject health-risk information when the information conflicts with their own behaviour because it threatens their self-integrity (the sense that one is a good person),. Thus, patients who do not adhere to their recommended fluid intake are more likely to question the accuracy or validity of

the information about the consequences of inadequate fluid treatment control. In turn, this is likely to reduce the potency of the information to sustain behaviour change.

Accumulated evidence suggests that a brief self-affirming activity, such as reflecting on the values we hold in high regard, can reduce resistance to threatening or dissonant health-risk information that conflicts with current beliefs and behaviour and increases the likelihood of behaviour change. Research examining the effectiveness of self-affirmation in the context of threatening health-risk information has largely focused on health behaviours affecting ostensibly "healthy" populations. These, include smoking cessation (Armitage, Harris, Hepton, & Napper, 2008), alcohol reduction (Armitage, Harris, & Arden, 2011), physical activity and healthy eating (Harris et al., 2014; D Jessop, Sparks, Buckland, Harris, & Churchill, 2014) and health screening attendance (van Koningsbruggen & Das, 2009). There is accumulating evidence that behavioural interventions based on self-affirmation theory can reduce resistance to unwelcome health risk information (Cohen & Sherman, 2014). Subsequently, self-affirmed participants typically find the health risk more threatening and personally relevant and report higher perceived self-efficacy and greater intentions towards the desired healthy behaviour (Epton & Harris, 2008; DC Jessop, Simmonds, & Sparks, 2009).

Recently, we conducted the first study to explore the unique effects of self-affirmation in a patient group living with a long-term condition. Specifically, the study piloted a self-affirmation theory based intervention aimed at improving phosphate binder medication adherence in patients receiving haemodialysis. A cluster randomised controlled trial demonstrated a significant effect of self-affirmation processes on improving patients' phosphate treatment control over 12 months (Wileman et al., 2014). However, the trial also revealed some unexpected findings; self-affirmed and control patients did not significantly

differ in their responses to the health risk information or their intentions to control their phosphate. Therefore it was unclear what had led to the observed clinical effect. It is possible that the effects of self-affirmation might have arisen due to hidden mediators not assessed in the study such as stress reduction (Logel & Cohen, 2012), response efficacy (Epton & Harris, 2008) or anticipated regret (van Koningsbruggen et al., 2014) and it is acknowledged that more research is needed to investigate this further. However, it was also considered that patients might not have ranked phosphate treatment high on their priorities compared with other, more demanding, aspects of treatment and this might have been reflected in the responses such as psychological threat (Karamanidou, Weinman, & Horne, 2013). Therefore, we chose to test the intervention in a new study, targeting a different treatment behaviour that is regarded as the most challenging for many patients receiving haemodialysis, restricting their fluid intake. Faced with a health-risk message about this particular aspect of treatment might arouse stronger cognitive and emotional responses and enable further examination of the effects of self-affirmation in this setting. Further, it was of interest to explore the possibility that an effect of self-affirmation, if observed again, could potentially be strengthened by repeated exposure of the intervention alongside the repeated exposure of the health risk information.

The present study therefore describes findings from a cluster randomised controlled trial which aimed to determine whether a self-affirmation theory based intervention altered patients' perceptions of health risk information about the importance of fluid treatment control. It was predicted that, compared with a control group, patients receiving a brief self-affirmation activity would: (i) have a more positive evaluation of the fluid health risk information (i.e. report higher perceived message quality, higher perceived threat and less message derogation), ii) report greater intention and self-efficacy to improve fluid control, and (iii) have lower IDWG levels at follow-up.

Materials and methods

Design The study was a two-armed pilot cluster randomised controlled trial comparing patients receiving information about the risks of inadequate fluid control to patients receiving the health-risk information following a brief self-affirmation activity. To reduce contamination, risk randomisation was by dialysis session (morning or afternoon, counterbalanced by day). The first sessions in each centre was allocated on the basis of a randomly generated sequence, and subsequent sessions in each centre by counterbalancing. The randomised sequence was independently generated. Patients were followed up at 1, 4, 12, 27, 40 and 52 weeks post intervention. The primary behavioural outcome was adherence to prescribed fluid intake, indicated by IDWG. Patient self-reported adherence was also assessed.

The self-affirmation intervention utilised in the current study was developed within studies assessing public health behaviour change and is relatively new in this clinical setting with just one prior study (Wileman et al., 2014). Therefore, there is limited evidence on which to estimate its potential effect and hence a pragmatic approach was adopted to estimate the required sample size following Medical Research Council guidelines. A target sample size of 90 was chosen to allow estimation of the variances to a precision equivalent to the standard deviation, allowing a robust estimate of effect size to be determined.

Patients and procedure

Eligible patients from six UK dialysis units within three National Health Service Trusts, were identified by a nephrologist and invited to participate, provided they: a) had a three month

average IDWG of >2.0 kg, b) were ≥ 3 months from initiation of dialysis, c) were fluent in reading English, d) had not been hospitalised in the previous 3 months, and e) did not have other conditions likely to compromise short-term survival. Efforts were made to ensure that all eligible patients were invited to participate to minimize sampling bias.

Ninety-one patients were recruited (Figure 1). Of all 662 patients present in the dialysis units, 159 met the eligibility criteria and 91 provided informed consent. There were no differences (assessed by demographic variables and length of time receiving dialysis) between study participants and patients who chose not to participate. Two patients did not complete baseline questionnaires and were excluded from the analysis. Data are reported on patients who completed the intervention measures (*n*=89).

Patients were provided with a Patient Information Sheet that had been approved by a National Health Service ethics committee, which specifically stated: This study aims to look at your views about fluid control information and your role in managing this. Patients completed questionnaires during their regular dialysis session. The questionnaires were identical except the intervention-related material that preceded the fluid treatment health-risk information, where patients self-affirmed or completed a matched-control task. Patients were then presented with health-risk information, after which they completed measures designed to assess their responses to the information and their intention to control fluid intake. The self-affirmation intervention was administered at baseline and a briefer version was repeated with each presentation of the health-risk information at 1, 3 and 6 months. The study was approved by the West of Scotland National Health Service ethics committee (ISRCTN: 18080970). The clinical team who provided all patient care was blinded but the researcher, who enrolled patients to the trial and collected data, was unblinded.

Materials and measures

Self-affirmation manipulation. Reed and Aspinwall's (Reed & Aspinwall, 1998) manipulation required participants to recall their past acts of kindness. It consists of 10 questions, for example 'Have you ever been concerned with the happiness of another person *yes or no?* Patients were encouraged to elaborate on their recollection for *yes* responses. Control patients completed 10 matched control questions (also from Reed and Aspinwall) with no self-affirming properties such as 'I think that the most aromatic trees in the world are pine trees. (Reed & Aspinwall, 1998).

Health-risk information. All patients received identical health-information about fluid control, with kind permission to reprint from The American Association of Kidney Patients (Hegel, 2002), which explained the possible consequences of high IDWG including muscles cramps, low blood pressure and the risk to their heart. Haemodialysis patients, not recruited for the present study, reviewed the questionnaires and health information prior to ethics review and confirmed that the information was appropriate and consistent with clinical advice.

Health-risk information responses

Immediately after reading the health information, patients were asked: "What did you think about the information you just read? Did you think it was . . ." to which they responded on 11 items (e.g. *not at all worrying – very worrying* and *not at all accurate – very accurate*). Four of these items, adapted from (Witte, 2011) were used to measure *perceived threat* namely *frightening, concerning, worrying* and *distressing*. *Perceived message quality* was measured

using five items, also adapted from (Witte, 2011), namely *relevant, interesting, persuasive, helpful* and *accurate*. *Message derogation* was measured using two items adapted from (DC Jessop et al., 2009) namely *overstated* and *exaggerated.*

Patients rated their intention and self-efficacy to control their fluid intake responding to three items for each construct e.g. *Do you intend to keep within your recommended fluid intake during the next month? (I definitely do – I definitely do not)* and *How likely is it that you will manage to keep within your recommended fluid intake? (Not all likely – Very likely).* Items were adapted from Armitage (Armitage et al., 2008). All items were measured on 7-point (1 to 7) scales. Self-reported responses were assessed after each presentation of the information.

Interdialytic weight gain (IDWG)

Adherence was assessed using IDWG (kg), which was collected at baseline, 1, 3, 6, 9 and 12 months. Clinical data that might contribute to the variation in IDWG levels, including patients' dry weight and dialysis adequacy (Kt/V) were extracted from dialysis unit databases.

Self-reported measures

Patients responded to a single item question to measure self-reported adherence "*During the past month how often have you stuck to your maximum recommend fluid intake?"* on a five point scale from *"None of the time - All of the time"*. Higher scores indicated higher adherence. Patients also completed the Patient Health Questionnaire(Kroenke, Spitzer, & Williams, 2003) to assess depressive symptoms and the Dialysis Thirst Inventory to measure perceived thirst (Bots et al., 2004).

Statistical methods

Post intervention evaluations of the responses to health-risk information were assessed using mean difference and 95% confidence intervals. Group differences were estimated using the intention-to-treat principle presented as unstandardised (i.e. original scale units) and as a standardised effects size (i.e. Cohen's *d*, standard deviation units). Tests for significant group differences were conducted using linear regression analyses, adjusting for baseline IDWG and cluster (unit, day and session).

To explore the effect of group on the clinical outcome (IDWG) over time, a multi-level linear regression model was estimated, incorporating a random intercept. Dummy variables for time, treatment group and time by group interaction terms were included as covariates to allow treatment effects to vary across the post-intervention assessments, In addition, the models include covariates for randomised cluster and baseline clinical marker. All covariates were entered in one step.

Results

The mean age of the sample was 60.7 (SD=1.6) years. Women (*n*=24) represented 26.7% of the sample. The majority of the sample was of white European ethnicity (70.8%), median length of time receiving haemodialysis was 3.8 (IQR=4.9) years. Patients were receiving adequate dialysis treatment as assessed by (Kt/V) (M=1.4, SD=.24). The mean IDWG assessed at baseline was 2.4 Kg (SD=.57) indicative of inadequate fluid control. Expressed as a percentage of dry-weight, the mean IDWG% was 3.2% (SD=.97). There were no significant differences between groups on any demographic and clinical factor, including baseline IDWG and comorbidity status, confirming successful randomisation (Table 1).

At twelve months, 60 patients were reassessed, representing an attrition rate of 33% (reasons for attrition are summarised in Figure 1). There were no demographic differences between completers and non-completers but there were some clinical and psychological differences. Non-completers had higher dialysis temperature (p<.01) and reported being more careful with their salt intake (p=.01).

All patients randomised to the intervention group (*n*=49) completed the self-affirmation task, with 71 % (*n*=35) responding Yes to at least 8 of the 10 kindness items. Twenty of the 49 patients did not elaborate following a positive (i.e. yes) response. Whether patients elaborated or not was not a significant predictor in the IDWG model below (p=.86).

Post intervention measures

Evaluation of the health-risk information

Contrary to predictions, there were no significant differences between self-affirmed and non-affirmed patients on post intervention ratings of perceived threat, perceived message quality, message derogation, and intention. Unadjusted mean ratings of perceived threat were higher (albeit non-significant) in affirmed compared to control patients (Cohen's *d*=.21, Table 2) but this effect was lost when adjusted for baseline IDWG and cluster. Responses assessed at 1, 3 and 6 months were also assessed and no group differences were observed.

IDWG (Kg) change over 12 months

A multilevel model, adjusting for baseline IDWG and cluster, was undertaken to assess whether group status (self-affirmation vs. controls) predicted IDWG reduction over 12

months. A significant group by time interaction was observed (X^2=26.2, *p*=.02, Fig. 2). The considerable reduction in IDWG from baseline to six months for self-affirmed patients appears to have contributed to this overall effect with a mean within-group IDWG reduction of .34 Kg (SD=.89), *p*=.02, Cohen's *d*=.55. For control patients over the same period, there was virtually no reduction in IDWG (M=.01Kg, SD=.67, *p*=.78, *d*=.06). The model adjusted mean difference (Table 3) between groups at six months was significant and with a medium effect size (*z*= -.1.9, *p*= 0.04, *d*=.40). After a further six months, both groups observe a slight increase in mean IDWG levels. This is discussed below.

Self-reported fluid adherence

Although not a primary outcome, it is desirable to obtain patient self-reported adherence measures in addition to a clinical outcome. At baseline, there was no differences in self-reported adherence to keeping within recommended fluid limits between self-affirmed (M: 3.4, SD=.81) and control patients (M: 3.4, SD=1.1), (t (84)=.07, *p*=.95, Cohen's *d*=.0). At one month follow up, self-affirmed patients' self-reported adherence scores increased whereas controls remained the same. The unadjusted mean difference (from baseline) between groups was significant (MD=-.34, t(68)=-2.0, p=<.05, Cohen's *d*=.49) though this effect was not maintained in adjusted analysis (see Table 3). At six months, self-affirmed patients' self-reported adherence remained higher than controls although the unadjusted difference from baseline was non-significant (MD=-28, t(52)=-1.06, p=.29, Cohen's d=.39).

Discussion

Inadequate fluid control as measured by IDWG is associated with poor outcomes in HD patients, thus interventions to help patients adhere to this behaviour are needed. This is just

the second study to evaluate the efficacy of a behavioural intervention based on self-affirmation theory among people with ESKD receiving haemodialysis. To our knowledge, it is one of only two studies to assess the unique effects of self-affirmation in a clinical setting such as ESKF (Wileman et al., 2014). This study aimed to determine whether a self-affirmation theory based intervention altered patients' perceptions of the health risk information and subsequent behaviour indicated by an improvement in fluid control (reduction in IDWG). An effect of self-affirmation on behaviour, indicated by a greater reduction in self-affirmed patients' improved IDWG levels, compared with controls, was established. Further, patients who self-affirmed, but not control patients, significantly increased their self-reported adherence levels at follow-up. However, support for some of the predictions derived from self-affirmation theory was not found. Specifically both the intervention and control groups held similar evaluations of the health risk information (regarding the need for adequate fluid control) and had similar intentions about controlling their fluid intake. These surprising null findings support those observed in our past study (Wileman, et al 2014). Accordingly, there is still a need to establish potential mediators of the observed effects.

Evaluation of the health risk information

Self affirmed patients did not differ significantly from controls in their responses to the health risk information. In some cases there was virtually no difference in the group means. Most patients reported high intentions to control fluid suggesting that they were already motivated to management their treatment and that there was limited scope to change. One exception to this lack of variation was patients' reported perceived threat at baseline though the difference remained non-significant. Self-affirmed patients rated the health message to be more threatening than controls with small effect sizes observed (d=.21), consistent with previous

research (Armitage et al., 2011; Good & Abraham, 2011). However the effect was lost when adjusted for clinical factors.

These results reflect the findings in the previous study which evaluated self-affirmation in a different treatment regimen, adherence to phosphate binding medication (Wileman et al., 2014). It was considered whether the lack of group differences in responses to health-risk information in the phosphate study was possibly due to the fact that patients might not rank phosphate treatment high on their priorities compared with other aspects of treatment and this might have been reflected in the responses. It was speculated that adherence to fluid control, a treatment that is particularly salient to patients (Karamanidou et al., 2013) might stimulate stronger feelings and that this might be evident in psychological responses to threat. However, the present study's findings suggest that this is not the case. It is likely therefore that the effects of affirmation have arisen due to hidden mediators not assessed and more research is needed to identify these measures further. One public health study that also reported no group effect on intention but observed an effect on behaviour change, established that Response Efficacy, the belief that undertaking the required behaviour will result in desirable outcomes and therefore remove the imminent threat, mediated the effects of self-affirmation(Epton & Harris, 2008). Van Koningsbruggen demonstrated that anticipated regret mediated the effects of self-affirmation on intentions (van Koningsbruggen et al., 2014). Stress reduction or mood enhancement is also a likely consideration which should be assessed in future studies (Cohen & Sherman, 2014).

It is also possible that the questionnaire items, developed in studies evaluating public health behaviour change, were not sufficiently effective in capturing these patients' feelings and thoughts about their treatment. The burden of treatment for patients living with ESKD is

immense and perhaps trying to isolate potentially complex perceptions with relatively straightforward questionnaire items regarding health risk information is not feasible. Instead, consideration needs to be given to the means by which such psychological responses could be assessed. Future work also needs to consider the actual means by which patients self-affirm. It is important to determine whether alternative self-affirmation manipulations lead to similar treatment effects to those observed here and whether they impact hypothesised mediators.

Assessing behaviour change

A significant adjusted mean IDWG reduction was observed over the study duration. On average patients who self affirmed managed to lower their IDWG by approximately one third of a kilogram, reducing their average IDWG of 2.5kg down to 2.1kg in a 7-day average assessment at six months. Like the previous phosphate study (Wileman et al., 2014), patients were shown repeated health-risk information on four occasions up to six months. After this time, only clinical data was collected. In the previous study the observed effects on serum phosphate were present over 12 months but in the current study, this does not appear to be the case. It is possible that in the case of fluid control behaviour, continued presentation of the health-risk information would perhaps increase the effect over time.

Assessing self-reported adherence complements the clinical proxy measure of adherence (IDWG). Self-affirmed patients reported a significant increase in adherence one month after the baseline intervention compared with controls and maintained similar levels over six months. Whilst these data do not necessarily provide any further insight as to the mechanisms that led to self-affirmed patients' mean reduction in IDWG post intervention, the fact that patients told us that they had managed to improve their fluid intake control is reassuring validation of the clinical outcome.

Strengths and limitations

The study has a relatively small sample size but benefitted from recruiting a diverse and realistic participant group. It is also acknowledged that the study sample had varying levels of IDWG and not all patients would have been categorised as high risk of poor treatment control. Future studies would benefit from ensuring that patients whose clinical measures indicate clear non-adherence and risk of consequences, are eligible to take part. The study experienced quite high attrition levels (33% at 12 months) but the reason for patients leaving the trial was for clinical reasons, transplantation being the commonest (14 patients (16%)). While all efforts were made to take each patient through the same process it is not possible to manage all potential confounding variables in a clinical environment and therefore the study cannot have achieved the control possible with laboratory based studies. However, ultimately such interventions need to be translatable into a clinical context and therefore this limitation can also be perceived as a strength, since this intervention approach has potential application within routine clinical practice. We did not control for residual kidney function since this was not routinely measured in most of the centres. However our selection of patients with baseline IDWG > 2kg would be likely to have excluded most patients with significant residual renal function. Furthermore any loss of residual renal function during the course of the study will have tended to increase IDWG rather than reduce it. The researcher was not blinded to treatment condition so the potential for bias exists. However this is a relatively small risk given the objective nature of the outcome variable (IDWG), the blinding of the clinical team providing all the patient care, and the absence of significant changes in self-report measures – potentially more vulnerable to researcher bias. Finally, this study gains from having a clinical proxy measure of behaviour change as well as patient self-report.

Summary

In summary, this investigation confirmed similar findings established in our previous study in respect of phosphate control (Wileman et al., 2014). A behaviour change intervention based on self-affirmation theory was associated with improved treatment control but the mechanism by which this apparent behaviour change occurred is uncertain.

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Figures and Tables

Fig 1. Patient recruitment flow chart

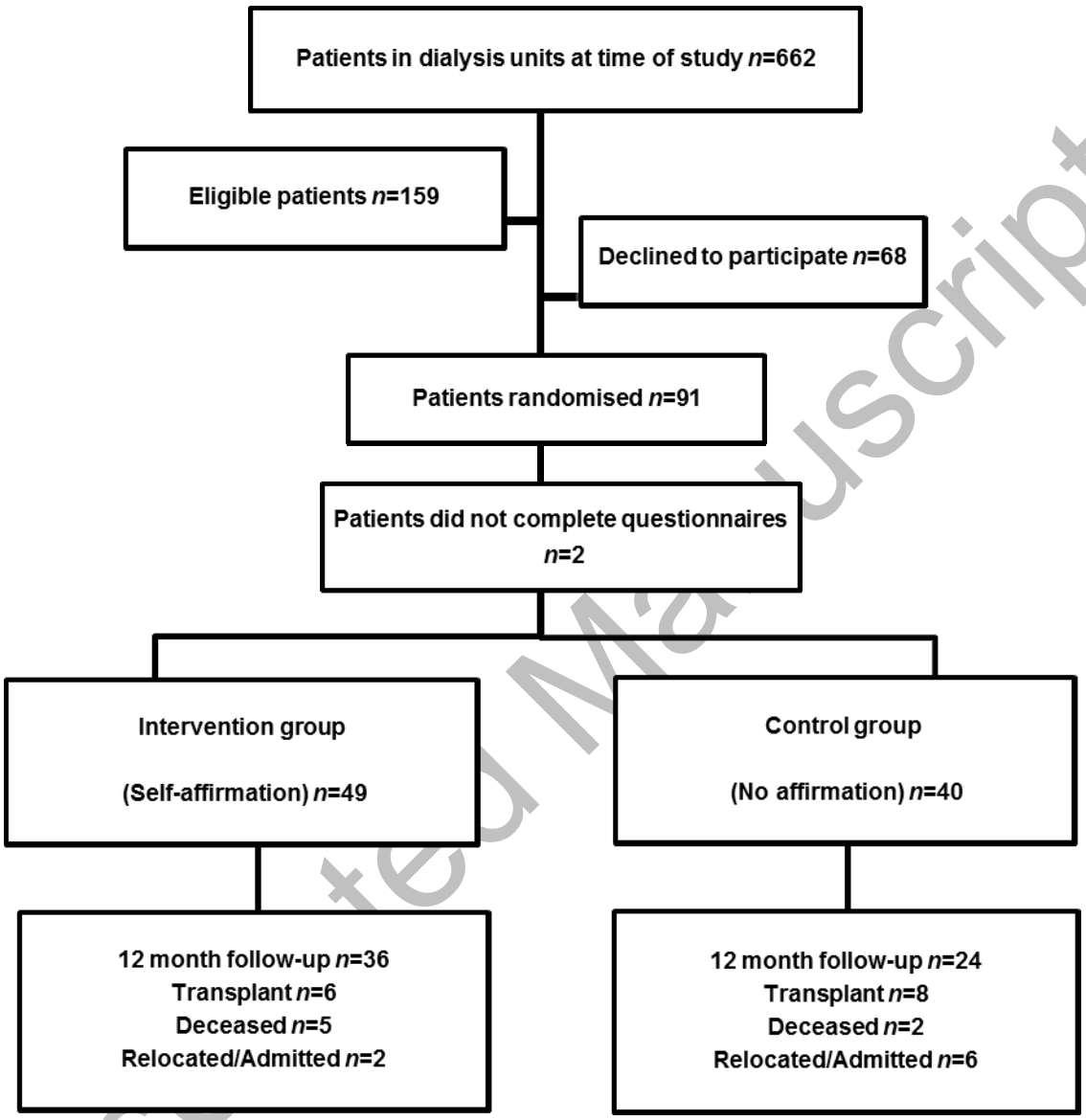


Table 1: Patient characteristics by group

		Control	Intervention
		Mean (SD)	Mean (SD)
Baseline measures	Scale	(n=40)	(n=49)
Women [n (%)]		10 [42]	14 [58]
Men [n (%)]		30 [46]	35 [54]
Age (years)		58.2[16.0]	62.8 [14.9]
Dialysis vintage (years) (Median [IQR])		2.9 [1.4 - 5.6]	2.6 [1.2 - 5.6]
Patients' self-reported adherence	1-5	3.4 [1.1]	3.4 [.81]
Perceived importance of fluid treatment control	1-7	6.2 [1.2]	5.9 [1.4]
Perceived thirst	0-35	19.5 [7.4]	20.8 [7.5]
Depressive symptoms (PHQ2)	0-6	1.7 [2.0]	2.3 [2.2]
Bio measures (three month average)			
Dry weight (Kg)		79.6 [22.0]	77.8 [16.1]
IDWG		2.45 [.54]	2.40 [.50]
IDWG as percentage of dry weight (Kg)		3.2 [.92]	3.2 [.77]
Kt/V		1.46 [.26]	1.41 [.23]
Dialysate sodium mmol/l		138 [1.5]	138 [1.5]
Dialysis temperature (°C)		36.1 [.72]	36.1 [.72]
Serum sodium mmol/l		138[2.8]	138 [2.4]

Data reported are means (SDs) unless otherwise stated. IQR: Interquartile Range.
PHQ2 : Patient Health Questionnaire

Table 2 Group differences in health risk information evaluation (at baseline)

			All	Control	Intervention	Mean difference [CI]			Adjusted mean difference [CI]			
Post intervention measures	Range	α		(n=40)	(n=49)		*p*	*effect size*		*t*	*p*>|t|	*effect size*
Perceived threat	4 - 28	.91	18.7 (7.3)	17.9 (7.0)	19.4 (7.5)	-1.5 (-4.6 to 1.6)	.34	.21	.44 (-2.8 to 3.7)	.27	.79	.10
Perceived message quality	5 - 35	.70	30.2 (4.7)	30.5 (3.7)	30.0 (5.4)	.54 (-1.4 to 2.5)	.59	.15	-1.3 (-3.4 to .71)	-1.3	.20	.24
Message derogation	2 - 14	r=.57**	5.0 (3.6)	5.3 (3.6)	4.7 (3.6)	.61 (-.91 to 2.1)	.43	.17	-.20 (-1.8 to 1.4)	-.24	.81	.10
Intention to control fluid	3 - 21	.82	16.3 (4.0)	16.2 (4.3)	16.4 (3.8)	-.23 (-1.9 to 1.5)	.79	.10	-.27 (-2.0 to 1.5)	-.31	.76	.10
Intention to control salt	4 - 21	.75	16.3 (4.4)	16.7 (4.5)	16.1 (4.3)	.59 (-1.3 to 2.4)	.53	.13	-.94 (-2.9 to 1.0)	-.95	.34	.18
Self-efficacy in controlling fluid	2 - 14	r=.48**	7.9 (3.4)	8.2 (3.5)	7.7 (3.3)	.46 (-.99 to 1.9)	.53	.13	-.45 (-2.0 to 1.1)	-.59	.56	.11
Self-efficacy in controlling salt	3 - 21	.63	14.5 (4.8)	14.9 (4.8)	14.2 (4.9)	.75 (-1.3 to 2.8)	.47	.15	-.70 (-2.8 to 1.4)	-.65	.51	.12

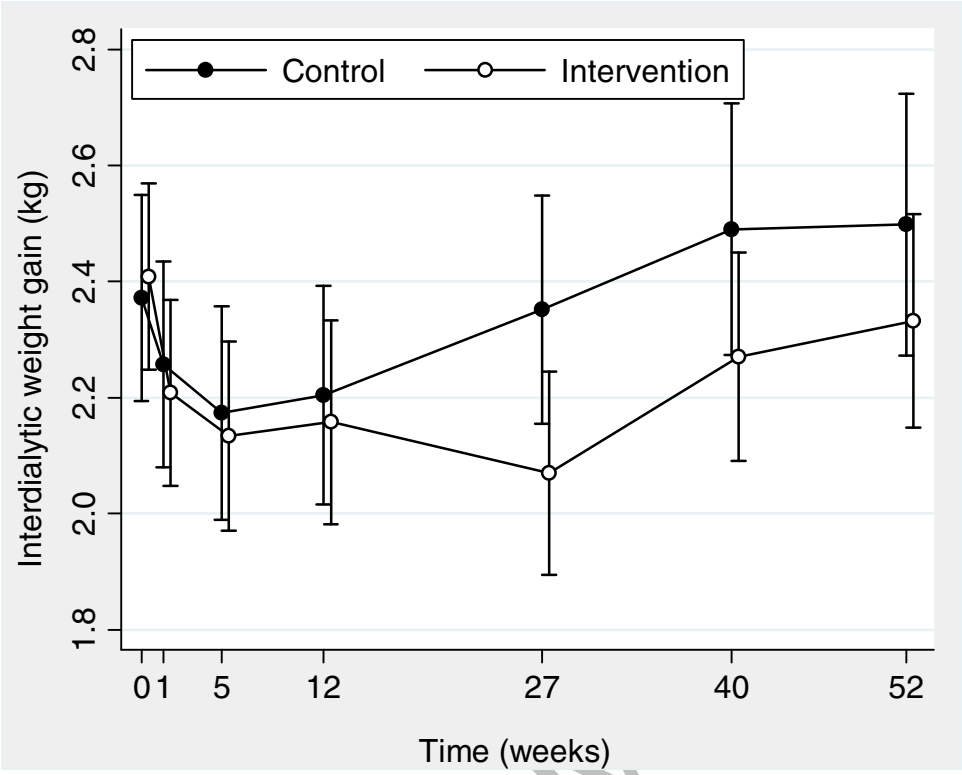
α= Cronbach's alpha. Pearson's *r* for two item scales. ** $p < .001$. Means [SD]. Unadjusted means [CI: 95% Confidence Intervals]. The mean effect size reported is the standardised mean difference *d*: Cohen's *d*. Adj Means: adjusted for baseline IDWG, experimental group and cluster (trust, unit, day and session).

Table 3 Group differences in interdialytic weight gain (IDWG) and self-reported adherence (MARS)

	All	Control	Intervention	Mean difference [CI]			Adjusted mean difference [CI]			
		(n=40)	(n=49)		*p*	effect size		z	*p*>|z|	effect size
Interdialytic weight-gain (IDWG)	**Kg**	**Kg**	**Kg**							
Baseline	2.4 (.57)	2.3 (.55)	2.5 (.57)	-.14 (-.38 to .09)	.23	.26	.04 (-.21 to .28)	.30	.77	.06
6 month follow-up (*n*=72)	2.2 (.90)	2.3 (.77)	2.1 (.99)	.17 (-.26 to .59)	.44	.22	-.28 (-.55 to -.01)	-2.1	.04	.43
Mean reduction at 6 months	**.19 (.81)**	**-.01 (.67)**	**-.34 (.89)**	**.33 (-.04 to .72)**	**.08**	**.50**	**-.32 (-.64 to .01)**	**-1.9**	**.05**	**.40**
12 month follow-up (*n*=60)	2.4 (.73)	2.4 (.65)	2.4 (.78)	.03 (-.36 to .41)	.89	.04	-.17 (-.46 to .13)	-1.1	.27	.23
Mean reduction at 12 months	**.02 (.74)**	**.17 (.62)**	**-.07 (.80)**	**.25 (-.14 to .63)**	**.21**	**.40**	**-.20 (-.55 to .15)**	**-.1.4**	**.25**	**.24**
Self-reported adherence (Scores:1-5)					*p*	effect size		*t*	*p*>|z|	effect size
Baseline	3.4 (.94)	3.4 (1.1)	3.4 (.81)	.01 (-.40 to .42)	.95	.01	-.06 (-.50 to .38)	-0.23	.78	.05
1 month follow-up (n=68)	3.5 (.91)	3.4 (.99)	3.6 (.82)	-.24 (-.67 to .19)	.27	.24	-.03 (-.51 to .45)	-0.13	.90	.02
Mean difference at 1 month	**.07 (.78)**	**-.13 (.76)**	**.24 (.76)**	**-.37 (-.74 to -.00)**	**<.05**	**.49**	**.18 (-.24 to .61)**	**.86**	**.40**	**.16**
6 month follow-up	3.4 (.92)	3.3 (.88)	3.5 (.97)	-.12 (-.64 to .40)	.65	.13	-.05 (-.56 to .45)	-0.2	.82	.04
Mean difference at 6 months	**.02 (.94)**	**-.17 (.72)**	**.10 (1.1)**	**-.28 (-.80 to .25)**	**.30**	**.39**	**.04 (-.50 to .57)**	**.16**	**.88**	**.03**

Means [SD]. Unadjusted means [CI: 95% Confidence Intervals]. Mean effect sizes: the effect size reported is the standardised mean difference d: Cohen's d. Adjusted mean difference for baseline IDWG, experimental group and cluster (trust, schedule and session).
Self-reported adherence [MARS scale: 1-5 where high scores represent higher adherence)

Fig 2 Model estimated adjusted interdialytic weight gain



Author(s) Statement of Conflict of Interest and Adherence to Ethical Standards

Authors Vari Wileman, Joseph Chilcot, Christopher J Armitage, Ken Farrington, David Wellsted, Sam Norton, Andrew Davenport, Maria Da Silva Gane, Gail Franklin, Robert Horne and Mike Almond declare that they have no conflict of interest. All procedures, including the informed consent process, were conducted in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2000.