**TITLE PAGE – REVISED VERSION (16/09/2013)**

**A Randomised Controlled Trial to Evaluate the Effectiveness of a Cognitive Behavioural Group Approach to Improve Patient Adherence to Peritoneal Dialysis Fluid Restrictions: A Pilot Study**

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**Manuscript word count:**

Abstract: 264

Manuscript body (excluding tables/references): 3302

**Abstract**

***Background***: Peritoneal dialysis (PD) requires patients to take an active role in their adherence to fluid restrictions. Although fluid non-adherence had been identified among this patient group, no specific interventions have been researched or published with the PD population. The current study sought to investigate whether an applied cognitive behavioural therapy (CBT) based intervention used among HD patients would improve fluid adherence among PD patients; utilising clinical indicators as used in practice.

***Methods***: 15 PD patients identified as fluid non-adherent were randomly assigned to an intervention group (IG) or a deferred-entry control group (CG). The study ran for a total of 21-weeks, with five data collection points; at baseline, post-intervention and at three follow-up points; providing a RCT phase and a combined longitudinal analysis phase. The content of the group intervention encompassed educational, cognitive and behavioural components, aimed to assist patients’ self-management of fluid.

***Results***: No significant differences in weight (kg) reduction were found in either phase and undesirable changes in blood pressure (BP) were observed. However, in the longitudinal phase, a statistically significant difference in oedematous status was observed at 6-week follow-up; which may be indicative of fluid adherence. Positive and significant differences were observed in the desired direction for measures of psychological wellbeing, quality of life and health beliefs; areas correlated with enhanced fluid adherence in other research.

***Conclusions***: This study reveals encouraging and significant changes in predictors of fluid adherence. Although there were no significant changes in weight change as a crude clinical measure of fluid intake, significant reductions in oedematous status were observed as a consequence of this CBT-based group intervention.

***Keyword:*** adherence, CBT, fluid, peritoneal dialysis, psychological intervention, randomised controlled trial

**Introduction**

Non-adherence is a recognised problem in the dialysis population for both haemodialysis (HD) and peritoneal dialysis (PD) patients.1 Most research in the literature focuses on non-adherence among HD patients,2-6 due to a more restrictive treatment regimen and a greater number of objective measurements available,7 such as interdialytic weight-gain (IWG). However, PD also requires a strict regime of dialysis exchanges and patients must take an active role in their adherence to fluid restrictions, dietary advice and medication regimes.8 Although assessment of non-adherence among PD patients ~~may~~ provides a greater challenge, as PD is a self-managed treatment taking place at home; studies have been conducted to investigate adherence with ~~the~~ PD exchanges ~~dialysis prescription~~. Non-adherence to exchanges administered ~~prescription~~ has been demonstrated in around one third of PD patients in objectively measured studies9-11 and in self-reported exchanges missed.12 Recognising a dearth of research related to fluid and dietary adherence, a recent study investigating self-reported adherence to the PD regimen found that 36% of patients did not adhere to their fluid restrictions;13 the authors identified that patients who were younger, male, or who had been receiving PD for longer demonstrated more non-adherent behaviour. Furthermore, documented clinical observations continue to reveal poor fluid self-management among PD patients14,15 and this is a recognised phenomenon among the PD care team.16

Research has demonstrated the importance of fluid adherence in terms of fluid retention (or ‘fluid overload’) and its impact on morbidity and mortality of PD patients.17,18 The consequences of fluid overload include shortness of breath, muscle cramping, dizziness, as well as hypertension, oedema (i.e. ankle, leg, facial), pulmonary oedema, cardiomyopathy and mortality.18 Achieving fluid balance is crucial in PD and interventions to reduce excess fluid consumption would therefore be beneficial to both patient health outcomes and the larger health economy.

Interventions specifically addressing fluid adherence have been conducted with the HD population with varying success;19-23 utilising several approaches including educational, psychological or a combination of both. Unfortunately, as far as the researchers are aware, there has been only one ~~have been no such specific interventions researched or~~ published study with the PD population.24 This ~~with the exception of a~~ ~~recent~~ research developed a nurse-led disease management programme to enhance general health outcomes in continuous ambulatory PD (CAPD) patients;24 however no significant change in fluid adherence between treatment and control groups were found. The lack of specific interventions may be ~~in~~ partly explained by the challenge ~~difficulty~~ in objectively measuring fluid intake ~~non-adherence~~ ~~compared to~~ as easily as HD, utilising IWG as indicator. Nonetheless, interventions need to be explored and developed among ~~the~~ PD patients ~~cohort~~, given the severe consequences associated with fluid overload ~~among this patient group~~.9 Therefore, the current study sought to investigate whether an applied psychological intervention used among HD patients would be effective in improving fluid adherence among PD patients; utilising clinical indicators as used in practice.

In a combined psycho-education group approach, Sharp *et al*23 demonstrated a statistically significant reduction in fluid-intake in a group of non-adherent HD patients. This group intervention used a multi-faceted design, which constituted a single theoretical method based on a cognitive behavioural therapy (CBT) approach. The group included components on education, behavioural techniques to engender self-management and monitoring cognitions to recognise associations between thoughts, feelings and behaviour; all of which are theoretical techniques utilised when adopting a CBT approach in chronic illness.25 Indeed, CBT-based interventions that incorporate all of these elements are believed to have an impact on long-term behaviour modification, in comparison to behavioural or educational interventions alone.1,25 Given its evidence-based implementation and encouraging results23, ~~to avoid re-inventing the wheel,~~ the researchers felt it would be worthwhile to investigate whether this particular intervention could be effective in enhancing fluid adherence among PD patients. The decision to replicate this particular intervention followed a meta-analysis conducted by the authors, indicating the significant findings compared to other fluid interventions; in addition the authors believed its delivery within a group setting would be suitable for the PD population, given their reduced outpatient attendance in comparison to HD. ~~Furthermore, replication of this original research~~~~23~~ ~~would allow the current researchers to make comparisons with previous findings.~~

The aim of the current study was to investigate whether the “Liquid Intake Programme” (“LIP”) (*renamed with permission from the original authors of the “Glasgow University Liquid-Intake Programme” (GULP)*); an applied and established intervention to enhance HD patient fluid restrictions, would be effective in improving fluid adherence among PD patients. Additionally, the research hoped to identify whether the group intervention had any effect on quality of life and psychological well-being; as well as impact on patient health beliefs and attributions. ~~These were investigated in the original study by Sharp~~ *~~et al~~*~~23~~ ~~and will therefore allow reference to the original study utilising HD patients.~~

**Methods**

***Participants:***

Ethical approval was granted by the Black Country NHS Research Ethics Committee, UK, on 23/12/2011 (reference: 11/WM/0355). Participants were recruited in December 2011 from one NHS Renal Service Home Therapies department in Wolverhampton, UK. PD patients meeting the inclusion criteria (Table 1) were identified by the PD clinical care team and invited to participate.

<<INSERT TABLE 1>>

***Design and Research Questions:***

A randomised controlled trial (RCT) design was employed, with a deferred-entry control group; to answer the primary research question: is the LIP intervention effective in improving fluid adherence among PD patients? Two secondary research questions were also considered: 1) does the LIP intervention have any impact on patients’ quality of life and emotional well-being? 2) Does the LIP intervention have any impact on patients’ health beliefs and attributions related to fluid restrictions?

Once all participants were recruited, they were randomised to the intervention group (IG) or the deferred-entry control group (CG) before baseline assessment. The study ran for a total of 21-weeks, with five data collection points; at baseline (T1), post-intervention (T2) and at three follow-up points (T3,T4,T5); providing a true RCT phase and longitudinal analysis phase. The IG received the intervention in weeks 1-4. The CG received the intervention in weeks 11-14; providing a control in both an extended baseline and replication of an intervention effect (Table 2).

<<INSERT TABLE 2>>

***Randomisation and Blinding:***

All consenting participants were allocated a number following recruitment and randomised into the IG or CG by simply drawing numbers out of a bag; allocated to each group in a sequential order. This method of randomisation was chosen to ensure the groups had equal sample sizes. There was no form of blinding in this study; due to the active nature of group attendance and participation, this could not be concealed.

***Intervention details:***

LIP was delivered in a group format (6-8 people) for one-hour sessions, once a week for four-weeks, in a hospital education room. The LIP intervention maintained the original group format and four-week session content (Table 3), with minor changes to the information presented about specific dialysis treatment (i.e. HD to PD); changes were made with the original authors’ permission.23 The groups were facilitated by a supervised Trainee Health Psychologist (JH), who adhered to the highly structured and formatted facilitators’ manual; allowing for replication between groups.

The content of the intervention utilised CBT techniques, encompassing educational, cognitive and behavioural components demonstrated in Table 3; aimed to assist patients’ self-management of fluid. Participants were provided with a structured LIP treatment manual; including record sheets, goal-setting sheets and daily planners for fluid intake and a relaxation CD. In accordance with CBT principles,25 participants were encouraged to complete homework between sessions; to maximise learning in everyday life.

<<INSERT TABLE 3>>

***Outcome measures:***

To answer the primary research question of whether LIP has improved fluid adherence, weight (kg) was used as the primary outcome measure. Secondary measures of blood pressure (BP: systolic/diastolic) and observable signs of oedema were also recorded; these three combined measures are used as clinical indicators of fluid overload in standard clinical practice. A clinically significant change in fluid adherence was identified *a priori* as a 2kg reduction in weight, accompanied by a decrease in blood pressure and change in oedematous status.

To answer the secondary research questions; to determine whether the LIP intervention had any impact on psychological well-being or quality of life, two well-established and standardised assessments were used: the Hospital Anxiety and Depression Scale (HADS)26 and the Short-Form 36 Health Survey (SF-36)27 (Table 4). To establish whether the intervention had any impact on an individual’s health beliefs or attributions relating to fluid adherence, a visual-analogue scale (VAS) ~~used in previous research~~~~23~~ was used23 (Table 4).

<<INSERT TABLE 4>>

***Data analysis:***

An intention-to-treat analysis was used for any participants lost to follow-up. In the current study there were no missing data for those who were retained in the study. Independent *t*-tests were used to examine any differences between the intervention and control group at baseline.

In the RCT phase (T0-T3), Analyses of Covariance (ANCOVA) were conducted for all continuous measures; with the baseline version of the outcome variable being treated as a covariate. For the categorical measure of oedema status, the McNemar test was conducted to indicate change in either direction. Data checks were performed to ensure homogeneity of regression slope, normal distribution of residuals and multivariate outliers were examined using plots of Cook’s distance and Leverage. When heterogeneity of regression was identified the interpretation was based on the ANCOVA with the added interaction between the covariate and the independent variable; this is known as an ANCHOET.28 Where multivariate outliers were identified, sensitivity analysis was conducted with and without such cases to see whether their presence affected the results.

A longitudinal analysis of the intervention effect was conducted by combing the IG and CG scores from their independent baseline, post-intervention (1-week) and 6-week follow-up time-points (i.e. IG measures from T1,T2,T3 and CG from T3,T4,T5); paired-sample *t*-tests were performed to investigate differences between baseline and each post-intervention assessment period.

Prospective power analysis calculations were based on predictions of non-adherent patient attendance at the PD clinic and expected throughput of 20 participants per group. With this expected sample size, in order to achieve power of 0.8,29 the study would need an effect size of **2** = 0.168.

**Results**

Forty-two eligible patients were identified to participate; 27 declined and the remaining 15 participants were randomly allocated to the IG or CG. Reasons for non-consent were not formally recorded, but included disinterest in attending a group or decline in health status. Participant characteristics are demonstrated in Table 5. Baseline data are recorded in Table 6; independent *t*-tests revealed no significant differences between the two groups on any outcome measures. However, in the case of anxiety and attributions B and C, the effect sizes were large; with the intervention group being less anxious and assigning more confidence in their own efforts to maintain fluid adherence (attribution B) and less difficulty in adhering to their fluid limits (attribution C).

<<INSERT TABLE 5>>

<<INSERT TABLE 6>>

***Intervention Impact***

The RCT period analysis investigated data from baseline to post-treatment (T1-T2) and from baseline to 6-week follow-up (T1-T3) between the IG and CG. Adjusted means for each continuous measure are included in Table 7; where the mean scores allow for differences in their baseline measures.

Analysis of covariance revealed no significant difference in weight between the IG and CG at either time-point. A significant difference in systolic BP between the groups was found post-intervention; however this was in the undesired direction; therefore LIP was ineffective in reducing the blood pressure of the IG significantly more than the CG. Likewise an undesired but significant effect on diastolic BP was observed between IG and CG at 6-week follow-up; however this ceased to be significant following sensitivity analyses (F1,11= 1.06; P=0.32). No significant differences were observed in psychological wellbeing or quality of life, with the exception of the SF-36 subscale mental health at follow-up. Significant differences in Attribution B and Health Belief C were revealed between groups post-intervention; however the latter ceased to be significant following sensitivity analyses removing 2 potential outliers (F1,12 =3.46; P=0.09); as the effect size is maintained (new **2** =0.26), it suggests the material effect was a consequence of reduced power by outlier removal, as opposed to a change in the actual result.

McNemar tests revealed no significant change in oedematous status within either period; CG oedema status remained stable throughout, whereas oedema was no longer present in 1 of the IG post-intervention and 2 of the IG at 6-week follow-up.

***Longitudinal Analysis***

Data were combined from both IG and CG to examine the interventions impact on all respective measures from baseline to post-intervention, post-intervention to 6-week follow-up and baseline to 6-week follow-up. In the former, only two significant differences were observed: in reduced HADS Anxiety (t14 = 2.32; P=0.034) and increased SF-36 subscale for Social Function (t14 = -2.73; P=0.016). No significant differences were observed from post-intervention to 6-week follow-up. However, from baseline to 6-week follow-up, eight significant differences were observed in the desired direction for HADS Anxiety and Total scores; SF-36 Overall score, Mental Health score and subscales of Role Physical and Social Function; and Health Beliefs A and C, recorded in Table 8. No significant differences were observed in weight or BP, however 5 participants were no longer oedematous at 6-week follow-up and the remainder did not change; this was observed as a significant effect (N=15; p=0.031).

***Supplementary Analysis (LIP Evaluation)***

Patient evaluation forms demonstrated a positive response to LIP in terms of its perceived usefulness (Table 9). The speed of the information delivered in the group was generally ~~ok~~ considered “just right”, although there were mixed responses for the total length of the ~~group~~ programme; 20% felt it was too long, 30% too short and 50% just right. Most patients always completed the LIP assignments, spending on average between 30-minutes to 1-hour per week.

<<INSERT TABLE 7>>

<<INSERT TABLE 8>>

<<INSERT TABLE 9>>

**Discussion**

Participation in LIP did not result in a significant improvement in fluid adherence as measured by weight; although a reduction was observed, it did not achieve a clinically significant 2kg reduction identified *a priori*. Similarly BP did not alter significantly and, within the RCT period, it was actually observed to increase in comparison to controls. However, the secondary measure of oedema status did achieve statistical significance when combining groups’ data from baseline to 6-week follow-up; providing an observable reduction in fluid retention in a significant proportion of participants. Similarly, in the original application of this intervention to HD patients,23 there were no significant changes in fluid intake, as measured by ~~interdialytic weight gain~~ IWG post-intervention, but at 10-week follow-up significant reductions were observed. This long-term effect was not explored formally in the current study; however within the IG a mean reduction in weight of 1.73kg (±2.96) from baseline to 16-week follow-up indicates promising but not statistically significant results. As Sharp *et al*23 similarly hypothesised, it may be reasonable to assume that further developed cognitive and behavioural self-management strategies continue following intervention conclusion. Similar longitudinal effects have been observed in comparable research with HD patients.30 Therefore, it would be worthwhile to investigate the longer-term impact on fluid adherence by reassessing measures beyond 16-weeks in future. Furthermore, the primary measures utilised in the current study, although more objective than self-report measures used in other PD research,13 remain crude outcomes in comparison to the use of IWG for HD. Consequently, it would be worth considering other forms of fluid measure for PD; indeed, application of bio-impedance devices, such as the ‘Body Composition Monitor’ (BCM), have recently been shown as effective means to assess fluid volume status.15 These devices have also indicated a wide spread of BP and fluid volume, meaning the measure of BP in the current study may not necessarily correlate with fluid adherence. However, anecdotal evidence from the current study revealed that due to three patients’ improved fluid adherence, clinical decisions were made to cease or reduce their BP medications; this echoes clinical findings of the importance of fluid adherence in maintaining normal BP.31

It is understood that dialysis, both PD and HD, can adversely affect psychological wellbeing and quality of life;32 indeed, anxiety, depression and a perceived reduction in quality of life have been identified as predictors of dialysis non-adherence.4,12,33,34 Therefore the significant improvements seen in these areas as a consequence of LIP are not only beneficial for overall psychological wellbeing and quality of life, but also in their predictive utility of enhanced adherence. Although LIP did not reveal any significant changes in the primary research question of fluid adherence; it did show positive and significant improvements in overall HADS scores and the anxiety domain, in addition to overall SF-36 scores and mental health domain, with notable improvements in subscales of ‘role physical’ and ‘social function’. The original intervention used among HD patients revealed no significant changes in these areas of psychological functioning;23 therefore no detrimental effects occurred as a result of the group intervention, but no positive impacts were seen either. Similarly, other interventions to improve self-management among PD patients have been ineffective in enhancing psychological wellbeing or quality of life.24 Consequently the current study has demonstrated that utilising a CBT group-approach has been effective in improving these aspects of functioning among the PD cohort; a significant and new finding.

Although the current study did not show significant changes in the RCT period, the combined data analysis identified positive and significant changes in the desired direction for two health beliefs. Changes in the perceived consequences of fluid overload and susceptibility of fluid overload consequences, supports the elements of the Health Belief Model in predicting behaviour change.35 Indeed health beliefs have been identified to influence adherence to the dialysis regime in several studies33,36,37 and are considered to be more important in motivating change over and above attributions.37 The educational elements of LIP (Table 3) ensured accurate messages of fluid overload were discussed, to correct inaccurate information and enhance beliefs. Changes in health beliefs were also observed in the application of this intervention to HD patients;23 therefore these studies combined provide evidence for the utility of a CBT-group to positively enhance cognitions associated with fluid adherence.

A lack of social support has been identified to predict non-adherence33 and, within LIP, the final week concentrated on maximising social support for the benefit of fluid adherence. Interestingly improvements were observed in social function in the combined longitudinal analysis at 6-week follow-up; this is a new finding and, according to the literature,33 may be predictive of enhanced fluid adherence.

While this study revealed encouraging and significant changes in psychological wellbeing, quality of life and health beliefs, unfortunately it failed to bring about a significant change in weight-reduction to indicate fluid adherence. Nonetheless, combining the significant change in oedematous status, with a reduction in weight, albeit non-significant, may be indicative of enhanced fluid adherence as a result of LIP. Furthermore, this research answers previous recommendations to utilise theoretical underpinnings to investigate intervention development, as well as explore the impact on distal outcomes of fluid adherence and self-management,38-40 including oedema, psychological wellbeing and quality of life. Therefore the researchers cannot ~~yet~~ fully dismiss the efficacy of piloting a previously trialled and successful CBT intervention for HD patients, with the PD cohort.

Although LIP shows potential among PD patients, the researchers are aware that despite an RCT design, a small sample size is a major limitation of the current study. Further research is required to strengthen the evidence-base of using LIP in practice to enhance fluid adherence; for the physiological measures of adherence, the researchers would recommend~~ed~~ utilising more robust measures of fluid intake, such as bio-impedance devices (i.e. the BCM).15 In terms of the prospective sample size required to achieve power, the quality of life measures demonstrated promise in the effect sizes seen in the current study. Therefore, if this research was replicated, in order to achieve a fully powered study, 24 participants would be needed per group.

~~The~~ Anecdotal evidence of utilising LIP in a UK renal service among PD patients ~~was~~ appears a feasible group to run and patient evaluations reveal~~ed~~ its perceived value. Additionally, ~~the~~ clinical ~~team~~ observations in removing/reducing BP medications, as well as changes in patients’ attitudes towards fluid intake, ~~as well as removing or reducing three individual’s BP medications. This is~~ demonstrate a positive impact to both patient health outcomes and cost-savings within the NHS. Therefore, although inconclusive, this research offers some tentative support to the application of CBT-based groups23 to enhance psychological wellbeing and possible fluid adherence among PD patients. However there remains some doubt about the efficacy of the intervention to reliably reduce fluid intake. More research is required to encourage health care providers to invest greater resources into multifaceted, psychosocial interventions among the renal population; so to reduce the costly implications of fluid overload in both health outcomes and financial resources.

**Acknowledgments:**

We would like to thank Dr John Sharp and his colleagues for providing the original GULP materials and granting permissions to edit and rename the programme for PD patients. We would also like to acknowledge and thank the Home Therapies department, for identifying eligible participants and supporting the research process and data collection. This research was supported by the Renal Services at the Royal Wolverhampton Hospitals NHS Trust.

**Transparency declarations**

The authors declare no conflicts of interest. The results presented in this paper have not been published previously in whole or part, except in abstract form.

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| **Table 1. Participant eligibility criteria** |
| ***Inclusion criteria:***   * PD patients identified as non-adherent to fluid restrictions (identified from standard clinical assessment**\*** * Patients receiving PD (CAPD and APD) for ≥ 3-months * PD patients ≥ aged 18 years * PD patients willing to participate in a group intervention * PD patients able to speak and/or read English |
| ***Exclusion criteria:***   * PD patients with identified cognitive impairment (e.g. dementia) * PD patients currently receiving psychological treatment/intervention * PD patients with significant vision or hearing impairment |
| **NOTES:**  \* Fluid non-adherence identified by fluid overload using standard clinical assessment and clinical judgment made by the PD medical team (consultant nephrologist and PD nurses). Clinical assessment based on:   * An increase in “ideal” weight, *and* * Observable signs of oedema (i.e. swelling of ankles, knees), *and* * Hypertension (high blood pressure)   ***Abbreviations***:  CAPD (Continuous Ambulatory Peritoneal Dialysis)  APD (Automated Peritoneal Dialysis) |

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| --- | --- | --- | --- |
| **Table 2. RCT design and participant involvement** | | | |
|  | **Week** | **IG** | **CG** |
| **RCT phase** | 0 **(T1)** | Baseline assessment | Baseline assessment |
| 1 | **LIP Intervention** | Standard Care |
| 2 |
| 3 |
| 4 |
| 5 **(T2)** | Post-treatment assessment | Continued baseline assessment |
| 6 | Standard Care | Standard Care |
| 7 |
| 8 |
| 9 |
| 10 **(T3)** | 6-Week Follow-up | Continued baseline assessment |
| **Longitudinal analysis** | 11 | Standard Care | **LIP Intervention** |
| 12 |
| 13 |
| 14 |
| 15 **(T4)** | 11-week Follow-up | Post-treatment assessment |
| 16 | Standard Care | Standard Care |
| 17 |
| 18 |
| 19 |
| 20 **(T5)** | 16-week Follow-up | 6-week Follow-up |

|  |  |
| --- | --- |
| **Table 3. CBT Components of the LIP Intervention** | |
| **COMPONENT** | **CONTENT**  Week 1: Introduction to LIP  Week 2: Goal Setting and Environmental Change  Week 3: Thought, Emotions and Behaviour  Week 4: Social Support and Programme Review |
| **Educational** | * Information on the importance of fluid restrictions and PD * Information on salt (sodium) * Introduction to self-monitoring * Importance of social support networks |
| **Behavioural** | * Techniques to enhance self-monitoring skills * Goal-setting and intention formation * Controlling environmental stimuli * Self-regulation * **Physical techniques** to manage physiological symptoms of stress and anxiety (progressive muscle relaxation; breathing-techniques) |
| **Cognitive** | * Identification of associations between thoughts, emotions and behaviour related to drinking * Monitoring and rating “the urge” to drink * Monitoring and evaluating unhelpful beliefs and thinking distortions impacting on drinking behaviour |
| **Note**: full treatment procedures are available from the authors | |

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| **Table 4. Outcome measures to address primary and secondary research questions** | |
| Outcome | **Measure** |
| **Fluid adherence** | - **Weight (kg):** measured using calibrated electronic scales; zeroed before use and recorded by the researcher (JH)  - **Blood Pressure** (Sys/Dias): measured using calibrated BP monitor; zeroed before use and recorded by the researcher (JH)  - **Oedematous status:** observable signs of oedema (“Yes” or “No”) were identified by clinical team; witnessed and recorded by the researcher (JH) |
| **Psychological wellbeing** | **HADS** 26: A self-report questionnaire with 14-items (7-items measure anxiety and 7-items measure depression), with a total overall score.  Scores for each domain range from 0-21 respectively; a lower score indicates better emotional well-being. |
| **Quality of Life** | **SF-36**27: a self-report questionnaire with 36 items, measuring quality of life in eight health dimensions (*1. physical functioning, 2. role limitations because of physical health problems, 3. bodily pain, 4. social functioning, 5. general mental health, 6. role limitations because of emotional problems, 7. Vitality, 8. general health perceptions*)  A ‘total score’ is calculated, along with an overall ‘Physical Health Score’ and ‘Mental Health Score’, in addition to individual scores for each dimension.  Scores range from 0-100; a higher score indicates better quality of life. |
| **Health Beliefs and Attributions** | **Health Beliefs and Attributions VAS**23: a 6-item self-report measure.  Health Beliefs: *A) to what extent do you believe excess fluid consumption is hazardous to your health? B) to what extent is it important for you to avoid excessive drinking? C) to what extent do you believe that restricting fluid intake will help you in preserving good health?*  Attributions: *A) what percentage of the time do you feel that you successfully adhere to your fluid restrictions? B) what percentage of the time do you believe that your adherence is due to your own efforts? C) in general, how difficult is it for you to resist fluid intake?*  Each question had a rating scale from 0-100. |

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| **Table 5. Participant Characteristics: N (%)\*** | | | | | | |
|  | |  | | **Total** | ***Intervention*** | ***Control*** |
| **Age, mean (years)** | | | | 60.1 (SD, 11.2) | *60 (SD, 14.1)* | *60.1 (SD, 12.2)* |
| **Gender** | |  | |  |  |  |
|  | Male | | | 14 (93.3) | *8 (100)* | *6 (85.7)* |
|  | Female | | | 1 (6.7) | *0 (0)* | *1 (14.3)* |
| **Marital Status** | |  | |  |  |  |
|  | Married | | | 12 (80) | *6 (75)* | *6 (85.7)* |
|  | Single | | | 2 (13.3) | *1 (12.5)* | *1 (14.3)* |
|  | Divorced | | | 1 (6.7) | *1 (12.5)* | *0 (0)* |
| **Employment Status** | | |  |  |  |  |
|  | Full-time employed | | | 3 (20) | *2 (25)* | *1 (14.4)* |
|  | Unemployed | | | 2 (13.3) | *1 (12.5)* | *1 (14.3)* |
|  | Retired | | | 10 (66.7) | *5 (62.5)* | *5 (71.4)* |
| **Education (highest)** | | |  |  |  |  |
|  | School leavers certificate | | | 1 (6.7) | *0 (0)* | *1 (14.3)* |
|  | Vocational qualification | | | 4 (26.7) | *1 (12.5)* | *3 (42.9)* |
|  | Further education diploma | | | 2 (13.3) | *2 (25)* | *0 (0)* |
|  | GCSE/O Levels | | | 1 (6.7) | *0 (0)* | *1 (14.3)* |
|  | University Degree | | | 1 (6.7) | *1 (12.5)* | *0 (0)* |
|  | Post-graduate training | | | 2 (13.3) | *0 (0)* | *2 (28.6)* |
|  | None | | | 4 26.7) | *4 (50)* | *0 (0)* |
| **Ethnic Group** | |  | |  |  |  |
|  | White (British) | | | 13 (86.7) | *8 (100)* | *5 (71.4)* |
|  | White (other) | | | 1 (6.7) | *0 (0)* | *1 (14.3)* |
|  | Asian (Indian) | | | 1 (6.7) | *0 (0)* | *1 (14.3)* |
| **Time on PD, mean (months)** | | | | 18.2 (SD, 14.25) | *16.63 (SD, 12.15)* | *20.0 (SD, 17.17)* |
| **Notes:**  \* indicated as % unless stated as standard deviation (SD) | | | | | | |

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| **Table 6. Baseline Measures by Randomised Treatment Group (mean, SD)\*** | | | | | | | | |
| **Outcome Measure** | | | |  | | **Intervention** | **Control** | **d** |
| **Weight (kg)** | | | |  | | 96.92 (11.63) | 92.39 (14.97) | -0.35 |
| **Oedema (n, %)** | | | |  | |  |  |  |
|  | *No* | | | | | 1 (12.5) | 0 (0) |  |
|  | *Yes* | | | | | 7 (87.5) | 8 (100) |  |
| **Blood Pressure (BP)** | | | | | | | | |
|  | BP Systolic | | | | | 153.0 (23.89) | 153.43 (30.6) | 0.02 |
|  | BP Diastolic | | | | | 90.38 (10.07) | 91.86 (7.2) | 0.17 |
| **HADS** | | |  | | |  |  |  |
|  | Anxiety | | | | | 8.63 (6.46) | 4.14 (3.44) | -0.80 |
|  | Depression | | | | | 5.38 (4.53) | 5.43 (3.15) | 0.01 |
|  | *Total* | | | | | 14.0 (10.25) | 9.57 (5.62) | -0.52 |
| **SF-36** | | | |  | |  |  |  |
|  | Total Score | | | | | 55.13 (23.52) | 55.29 (16.78) | 0.01 |
|  | Physical Health Domain | | | | | 55.5 (23.85) | 48.86 (23.55) | -0.29 |
|  | Mental Health Domain | | | | | 53.88 (25.27) | 56.0 (15.74) | 0.10 |
|  | | Physical Function | | | | 58.13 (23.75) | 55.71 (24.05) | -0.10 |
|  | | Role-Physical | | | | 54.38 (28.21) | 46.43 (39.34) | -0.24 |
|  | | Bodily Pain | | | | 60.25 (23.68) | 59.43 (22.97) | -0.04 |
|  | | General Health | | | | 56.38 (26.41) | 39.43 (21.76) | -0.68 |
|  | | Vitality | | | | 48.13 (27.38) | 43.57 (28.68) | -0.17 |
|  | | Social Functioning | | | | 48.63 (22.49) | 53.86 (28.57) | 0.21 |
|  | | Role Emotional | | | | 45.75 (46.96) | 61.86 (40.59) | 0.37 |
|  | | Mental Health | | | | 70.0 (25.75) | 81.14 (7.90) | 0.56 |
| **Health Beliefs** | | | | |  |  |  |  |
|  | Question A | | | | | 85.63 (17.82) | 82.86 (18.68) | -0.16 |
|  | Question B | | | | | 91.25 (10.94) | 83.57 (18.42) | -0.52 |
|  | Question C | | | | | 88.75 (10.94) | 73.21 (31.84) | -0.66 |
| **Attributions** | | | | |  |  |  |  |
|  | Question A | | | | | 75.63 (18.21) | 71.43 (17.25) | -0.24 |
|  | Question B | | | | | 77.75 (20.44) | 93.57 (9.88) | 0.89 |
|  | Question C | | | | | 66.88 (24.49) | 42.14 (29.27) | -0.86 |
| **NOTES:**  \* Except Oedema ratings (categorical data), which are stated as: N, (%) | | | | | | | | |

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| **Table 7. RCT analysis: ANCOVA of IG and CG of outcome measures from T1-T2 and T1-T3** | | | | | | | | |
| **Outcome measure** | | **IG Adjusted mean** | **CG Adjusted mean** | **df** | **F** | **2** | **P** |  |
| **Weight (kg)**T1-T2 | | 94.259 | 94.254 | 1,12 | <0.001 | <.001 | .993 |  |
| **Weight (kg**) T1-T3 | | 94.022 | 94.474 | 1,12 | 0.148 | .012 | .707 |  |
| **Blood Pressure (BP)** | |  |  |  |  |  |  |  |
|  | BP systolic T1-T2 | 144.930 | 140.504 | 1,12 | 4.946 | .310 | .048\* | † |
|  | BP systolic T1-T3 | 155.351 | 146.870 | 1,11 | 4.250 | .279 | .064 | † |
|  | BP diastolic T1-T2 | 87.428 | 84.797 | 1,12 | 0.300 | .024 | .594 |  |
|  | BP diastolic T1-T3 | 88.049 | 76.386 | 1,11 | 9.314 | .459 | .011\* | †⌂ |
| **HADS** | |  |  |  |  |  |  |  |
|  | Anxiety T1-T2 | 5.177 | 5.655 | 1,12 | 0.127 | .010 | .728 |  |
|  | Anxiety T1-T3 | 5.548 | 6.231 | 1,12 | 0.211 | .017 | .654 |  |
|  | Depression T-T2 | 5.021 | 5.548 | 1,12 | 0.118 | .010 | .737 |  |
|  | Depression T1-T3 | 5.146 | 5.262 | 1,12 | 0.009 | .001 | .925 |  |
|  | Total T1-T2 | 10.179 | 11.224 | 1,12 | 0.190 | .016 | .671 |  |
|  | Total T1-T3 | 10.701 | 11.485 | 1,12 | 0.098 | .008 | .760 |  |
| **SF-36** | |  |  |  |  |  |  |  |
|  | Total Score T1-T2 | 59.944 | 47.207 | 1,12 | 1.989 | .142 | .184 |  |
|  | Total Score T1-T3 | 59.569 | 52.779 | 1,12 | 1.275 | .096 | .281 |  |
|  | Physical Health Score T1-T2 | 54.120 | 39.435 | 1,12 | 3.430 | .222 | .089 |  |
|  | Physical Health Score T1-T3 | 55.735 | 46.874 | 1,12 | 1.682 | .123 | .219 |  |
|  | Mental Health Score T1-T2 | 63.072 | 51.775 | 1,12 | 1.089 | .083 | .317 |  |
|  | Mental Health Score T1-T3 | 60.014 | 56.841 | 1,12 | 0.280 | .023 | .606 |  |
|  | *Physical Function T1-T2* | 58.914 | 54.098 | 1,12 | 0.486 | .039 | .499 |  |
|  | *Physical Function T1-T3* | 58.334 | 46.904 | 1,12 | 1.771 | .129 | .208 |  |
|  | *Role Physical T1-T2* | 46.200 | 20.771 | 1,12 | 2.794 | .189 | .120 |  |
|  | *Role Physical T1-T3* | 62.403 | 34.396 | 1,12 | 2.879 | .194 | .115 |  |
|  | *Bodily Pain T1-T2* | 58.162 | 45.244 | 1,12 | 1.012 | .078 | .334 |  |
|  | *Bodily Pain T1-T3* | 56.723 | 54.603 | 1,12 | 0.041 | .003 | .843 |  |
|  | *General Health T1-T2* | 54.096 | 42.462 | 1,12 | 1.157 | .088 | .303 |  |
|  | *General Health T1-T3* | 52.363 | 48.728 | 1,12 | 0.073 | .006 | .791 |  |
|  | *Vitality T1-T2* | 53.854 | 32.738 | 1,12 | 2.883 | .194 | .115 |  |
|  | *Vitality T1-T3* | 49.229 | 47.310 | 1,12 | 0.033 | .003 | .859 |  |
|  | *Social Function T1-T2* | 73.535 | 62.674 | 1,12 | 0.634 | .050 | .441 |  |
|  | *Social Function T1-T3* | 70.651 | 55.685 | 1,12 | 1.918 | .138 | .191 |  |
|  | *Role Emotional T1-T2* | 58.823 | 51.917 | 1,12 | 0.089 | .007 | .771 |  |
|  | *Role Emotional T1-T3* | 54.057 | 57.363 | 1,12 | 0.023 | .002 | .881 |  |
|  | *Mental Health T1-T2* | 75.129 | 67.853 | 1,12 | 0.460 | .037 | .510 |  |
|  | *Mental Health T1-T3* | 74.193 | 89.171 | 1,11 | 13.526 | .551 | .004\* | † |
| **Health Beliefs Questions** | |  |  |  |  |  |  |  |
|  | Question A T1-T2 | 95.573 | 68.202 | 1,12 | 3.863 | .244 | .073 |  |
|  | Question A T1-T3 | 94.700 | 80.771 | 1,12 | 4.101 | .255 | .066 |  |
|  | Question B T1-T2 | 94.946 | 78.919 | 1,12 | 2.394 | .166 | .148 |  |
|  | Question B T1-T3 | 91.387 | 87.415 | 1,12 | .482 | .039 | .501 |  |
|  | Question C T1-T2 | 89.682 | 74.221 | 1,12 | 5.018 | .295 | .045\* | †⌂ |
|  | Question C T1-T3 | 92.432 | 89.006 | 1,12 | .450 | .036 | .515 |  |
| **Attribution Questions** | |  |  |  |  |  |  |  |
|  | Question A T1-T2 | 75.640 | 82.412 | 1,12 | 1.034 | .079 | .329 |  |
|  | Question A T1-T3 | 82.562 | 78.143 | 1,12 | 0.371 | .030 | .554 |  |
|  | Question B T1-T2 | 90.446 | 94.715 | 1,11 | 6.333 | .365 | .029\* | † |
|  | Question B T1-T3 | 89.415 | 76.026 | 1,12 | 1.992 | .142 | .184 |  |
|  | Question C T1-T2 | 41.584 | 45.261 | 1,12 | 0.051 | .004 | .825 |  |
|  | Question C T1-T3 | 41.380 | 39.494 | 1,12 | 0.010 | .001 | .920 |  |
| **Notes**:  † indicates ANCOHET interaction  ⌂ sensitivity analysis performed and material effect found: no longer significant  \* indicates significant difference | | | | | | | | |

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| **Table 8. Combined longitudinal analysis from baseline to 6-week follow-up** | | | | | | | | | | | | |
| **Outcome Measure** | | **Baseline mean** | ***SD*** | **6-wk Follow-up mean** | ***SD*** | **Mean difference (baseline – follow-up)** | ***SD*** | **Cohen’s d** | ***t*** | **P**  **(2-tailed)** | 95% Confidence Interval of the difference | |
| Lower | Upper |
| **Weight (kg)** | | 94.55 | *13.69* | 93.86 | *14.20* | 0.69 | *1.97* | 0.35 | 1.36 | 0.20 | -0.40 | 1.78 |
| **Blood Pressure** | |  |  |  |  |  |  |  |  |  |  |  |
|  | BP Systolic | 150.20 | *22.72* | 146.53 | *26.55* | 3.67 | *13.64* | 0.27 | 1.04 | 0.32 | -3.88 | 11.22 |
|  | BP Diastolic | 84.87 | *17.11* | 85.07 | *9.62* | -0.20 | *14.86* | -0.01 | -0.05 | 0.96 | -8.43 | 8.03 |
| **HADS** | |  |  |  |  |  |  |  |  |  |  |  |
|  | Anxiety | 6.47 | *5.55* | 5.20 | *5.75* | 1.27 | *1.94* | 0.65 | 2.52 | 0.02\* | 0.19 | 2.34 |
|  | Depression | 5.33 | *3.83* | 4.40 | *3.74* | 0.93 | *2.22* | 0.42 | 1.63 | 0.13 | -0.30 | 2.16 |
|  | Total | 11.80 | *8.39* | 9.60 | *9.05* | 2.20 | *3.71* | 0.59 | 2.30 | 0.04\* | 0.15 | 4.25 |
| **SF-36** | |  |  |  |  |  |  |  |  |  |  |  |
|  | Total Score | 54.07 | *20.83* | 61.33 | *19.50* | -7.27 | *10.44* | -0.70 | -2.70 | 0.02\* | -13.05 | -1.49 |
|  | Physical Health Score | 50.27 | *21.82* | 53.87 | *20.84* | -3.60 | *10.87* | -0.33 | -1.28 | 0.22 | -9.62 | 2.42 |
|  | Mental Health Score | 55.73 | *20.91* | 63.87 | *20.29* | -8.13 | *13.05* | -0.62 | -2.41 | 0.03\* | -15.36 | -0.90 |
|  | *Physical Function* | 52.33 | *26.92* | 54.67 | *24.96* | -2.33 | *11.63* | -0.20 | -0.78 | 0.45\* | -8.77 | 4.11 |
|  | *Role Physical* | 44.00 | *33.60* | 56.00 | *34.91* | -12.00 | *25.48* | -0.47 | -1.82 | 0.09 | -26.11 | 2.11 |
|  | *Bodily Pain* | 57.53 | *21.01* | 60.13 | *22.04* | -2.60 | *17.57* | -0.15 | -0.57 | 0.58 | -12.33 | 7.13 |
|  | *General Health* | 49.93 | *26.89* | 51.40 | *27.23* | -1.47 | *21.76* | -0.07 | -0.26 | 0.80 | -13.52 | 10.58 |
|  | *Vitality* | 47.00 | *24.70* | 47.00 | *23.28* | 0.00 | *20.44* | 0.00 | 0.00 | 1.00 | -11.32 | 11.32 |
|  | *Social Function* | 52.80 | *22.25* | 71.00 | *23.95* | -18.20 | *23.53* | -0.77 | -3.00 | 0.01\* | -31.23 | -5.17 |
|  | *Role Emotional* | 53.33 | *45.11* | 71.13 | *41.55* | -17.80 | *43.48* | -0.41 | -1.59 | 0.14 | -41.88 | 6.28 |
|  | *Mental Health* | 75.73 | *20.64* | 79.20 | *25.08* | -3.47 | *12.99* | -0.27 | -1.03 | 0.32 | -10.66 | 3.73 |
| **Health Belief Questions** | |  |  |  |  |  |  |  |  |  |  |  |
|  | Question A | 83.20 | *17.24* | 91.67 | *14.10* | -8.47 | *13.35* | -0.63 | -2.46 | 0.03\* | -15.86 | -1.08 |
|  | Question B | 88.20 | *14.81* | 92.33 | *9.42* | -4.13 | *8.01* | -0.52 | -2.00 | 0.07 | -8.57 | 0.30 |
|  | Question C | 87.17 | *14.36* | 92.80 | *11.23* | -5.63 | *9.10* | -0.62 | -2.40 | 0.03\* | -10.67 | -0.59 |
| **Attribution Questions** | |  |  |  |  |  |  |  |  |  |  |  |
|  | Question A | 76.33 | *16.17* | 80.17 | *19.51* | -3.83 | *22.36* | -0.17 | -0.66 | 0.52 | -16.21 | 8.55 |
|  | Question B | 79.97 | *18.65* | 86.00 | *17.03* | -6.03 | *15.81* | -0.38 | -1.48 | 0.16 | -14.79 | 2.72 |
|  | Question C | 53.83 | *28.74* | 39.00 | *33.16* | 14.83 | *30.84* | 0.48 | 1.86 | 0.08 | -2.25 | 31.91 |
| **Notes:**  DF = 14  Improvement indicated by a positive *t* value on Weight, BP and HADS; and a negative *t* value on the SF-36.  \* indicates significant difference at p < .05 | | | | | | | | | | | | |

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| **Table 9. LIP Anonymous Patient Evaluation *(returned: N = 11)*** | | |
| **Evaluative Aspect** | **Rating** | **N (%)** |
| **Usefulness of LIP:**  *(100% useful; 75%; 50%; 25%; to 0% useful)* | 100%  75%  50%  0% | 6 (54.55)  2 (18.18)  2 (18.18)  1 (9.09) |
| **LIP assignments were completed:**  *(Always; Most weeks; Some weeks; Rarely; Never)* | Always  Most weeks  Some Weeks | 8 (72.73)  2 (18.18)  1 (9.09) |
| **Time per week spent on LIP assignments:**  *(<30mins; 30mins-1hour; 1-1.5hour; 1.5-2hours; >2hours)* | <30 minutes  30minutes – 1hour  1 – 1.5hour | 3 (27.27)  6 (54.55)  2 (18.17) |
| **Length of LIP group\*:**  *(too short; too long; just right)* | Too short  Too long  Just right | 3 (30)  2 (20)  5 (50) |
| **Speed of LIP group progression\*:**  *(too slow; too fast; just right)* | Too slow  Just right | 1 (10)  9 (90) |
| **Helpfulness of therapist style:**  *(100% helpful; 75%; 50%; 25%; to 0% helpful)* | 100%  82%  75% | 6 (54.55)  2 (18.18)  3 (27.27) |
| **Notes:**  \*n=10 as questions not completed | | |