The BCM – Body Composition Monitor for managing fluid in people having dialysis

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Summary

The BCM – Body Composition Monitor is a bioimpedance device to measure the fluid status of people having dialysis for chronic kidney disease. Poor fluid management is associated with increased cardiovascular risk, further kidney damage and higher mortality. Five studies of generally low quality that compared the device with clinical judgement reported better fluid management with the BCM – Body Composition Monitor across several outcome measures. These improvements were statistically significant in 4 studies. The list price of the BCM – Body Composition Monitor package is £5750 (excluding VAT), which includes all the elements necessary for use. Each reading needs 4 disposable electrodes and packs of 40 electrodes cost £30.
<table>
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<th>Product summary and likely place in therapy</th>
<th>Effectiveness and safety</th>
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<td>The BCM – Body Composition Monitor is designed to measure fluid status during haemodialysis or peritoneal dialysis for chronic kidney disease. It is more likely to be used in haemodialysis because this is a more common procedure.</td>
<td>Five studies (4 of randomised design) compared fluid management using the BCM – Body Composition Monitor with current management methods in haemodialysis patients (4) and peritoneal dialysis patients (1). None of the studies were done in the UK and they were generally of low quality.</td>
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<td>The device can be used in dialysis clinics or during home visits and is in addition to current clinical judgement of fluid status, which is based on symptoms, current medication, residual kidney function and blood pressure.</td>
<td>Four studies reported significantly better fluid management, across several outcome measures, when the BCM – Body Composition Monitor was compared with clinical judgement alone. In the fifth study, the improvement in outcome measures with BCM – Body Composition Monitor was not statistically significant.</td>
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<td>None of the studies reported any adverse events related to the use of the BCM – Body Composition Monitor.</td>
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## Technical and patient factors

- The BCM – Body Composition Monitor is a bioimpedance device with integrated software that measures fluid status. This information can then be used to help determine an optimum target weight for people having dialysis.

- The person being monitored lies down and electrodes are attached to 1 hand and 1 foot on the same side of the body. These electrodes are connected to the monitor and fluid status is measured. The process takes between 5 and 10 minutes.

- Data are displayed on an inbuilt screen or can be transferred to a computer, for further analysis.

- The device needs minimal training to operate, but good clinical knowledge is needed to interpret the results and use them to guide treatment decisions.

- The BCM – Body Composition Monitor should not be used in an intensive care setting, where interference from other devices affects the accuracy of the measurements.

## Cost and resource use

- The BCM – Body Composition Monitor package has a list price of £5750 (excluding VAT). This contains 40 disposable electrodes.

- Each measurement needs 4 disposable electrodes. Additional packs of 40 electrodes cost £30.

## Introduction

The kidneys act as filters, removing waste from the blood and expelling it in urine. Chronic kidney disease (CKD) is a long-term condition in which the kidneys do not work effectively. There are many causes of CKD, including hereditary disease and autoimmune disorders, but the most common...
causes are high blood pressure or diabetes. People who are older, are overweight, smoke, consume excess alcohol, have limited exercise or have a poor diet are at increased risk of CKD. It is more common in people of African-Caribbean or south Asian family origin (NHS Choices 2015a).

The progression of CKD can be measured according to 5 stages of severity. According to NICE guidance on chronic kidney disease, each stage is defined by the glomerular filtration rate (an estimation of how much fluid is filtered from the blood by the kidneys every minute), markers of kidney damage that can be detected in the urine, and by medical imaging or histological examination. In the most severe stage of the disease, stage 5, the kidneys will be working at 15% or less of their normal function. At this point the person will need to start treatment in the form of conservative management, dialysis or kidney transplantation (Guy's and St Thomas' NHS Foundation Trust 2012). Collectively these treatments are called renal replacement therapy (RRT).

Conservative management of CKD is a term for treatments that try to preserve remaining kidney function, control the symptoms of kidney disease and improve wellbeing without resorting to dialysis or kidney transplantation (Queen Elizabeth Hospital Birmingham 2013). Dialysis involves removing waste products and excess fluid from the bloodstream (NHS Choices 2015c). There are 2 types of dialysis treatment, haemodialysis (HD) and peritoneal dialysis (PD). In HD, blood is passed to a machine for filtration, and then returned to the person. During PD, fluid is passed into the peritoneal cavity, where it draws waste and excess fluid from the blood vessels lining the cavity, after which it is drained from the cavity.

In December 2013, there were 56,940 adults having RRT in the UK and 48% of these were having dialysis treatment. Use of the 2 types of dialysis varies across regions and populations in the UK. HD is more widely used than PD in adults, accounting for around 80% of all dialysis procedures, whereas 40% of children on dialysis have PD (The Renal Association 2014).

HD can be done at home or at the hospital, with treatments usually carried out 3 times a week, each lasting 4 hours (NHS Choices 2015c). PD can either be done 4 times a day while the person goes about their daily activities, or during the night, while the dialysis machine controls the exchange of fluids (mykidney 2015).

People having HD are usually advised to restrict their diet, to avoid food and drinks high in sodium, potassium and phosphorous, and to closely monitor their fluid intake. Dietary controls are less strict for people on PD and those who have some remaining kidney function (NHS Choices 2015c).

To calculate the amount of fluid to be removed during dialysis, a person will be assigned a target weight. This is how much a person should weigh in the morning if they have PD, or at the end of an
HD session. One litre of water weighs 1 kg, and so differences between current and target weight guide the amount of fluid to be removed during dialysis. The target weight is not the same as the normally hydrated weight (the weight of a healthy person with a normal amount of fluid in their body). The target weight may be set higher or lower than the normally hydrated weight. For example, people with congestive heart failure are more likely to have fluid retention in the lungs and so may have a target weight below their normally hydrated weight. Dehydration is not well tolerated by some people, so they may have a target weight above their normally hydrated weight. Because of the length of time between HD treatments (2–3 days), the target weight must also account for expected fluid gain between sessions (Lindley and Keane, 2014).

In HD, the dialysis machine is programmed to remove a specific quantity of fluid, called the ultrafiltration volume, over a specified period of time. The rate at which fluid is removed is called the ultrafiltration rate (Jaeger and Mehta, 1999). In addition to changing the ultrafiltration rate, the frequency and duration of HD treatments may be altered to increase the amount of fluid removed (The Renal Association 2013). In PD, glucose is usually used in the dialysis fluid to draw fluid from the blood. Stronger glucose concentrations, exchanged more frequently, will result in more fluid being removed (Ontario Renal Network 2015; RenalMed 2015).

Maintaining the correct amount of fluid in the body is essential for people having dialysis. If the prescribed target weight is not set correctly, too much or too little fluid will be removed during dialysis. If too little fluid is removed, the person can develop oedema (swelling) of the hands, feet and face as excess fluid collects in the tissues. This excess fluid may also collect in the lungs leading to shortness of breath (NHS Technology Adoption Centre 2011). Excess fluid in the body is called fluid overload (Kidney Patient Guide 2012). Removing too much fluid leads to dehydration, which can cause cramps, dizziness and tiredness (NHS Technology Adoption Centre 2011).

Over the long term, continued fluid imbalance can result in a person's blood pressure being too high or too low, although the relationship is complex and differs between individuals (Lindley and Keane 2014). Poor control of blood pressure (too high or too low) can lead to heart disease; low blood pressure can also cause further reductions in kidney function (NHS Technical Adoption Centre 2011; Lindley and Keane 2014; Sulowicz and Radziszewski 2006). Over-hydration in people having dialysis is strongly linked to left ventricular hypertrophy (thickening of the left heart wall), which increases the risk of heart attack, stroke and irregular heart beat (arrhythmia; Ozkahya et al. 1998; Blood Pressure UK 2008).

Some studies have estimated the prevalence and associated health consequences of fluid imbalance in people having dialysis. All these studies involved bioimpedance spectroscopy
measurements obtained by using the BCM – Body Composition Monitor. Because this is the focus of this briefing these studies are discussed in the clinical evidence section of this report.

**Technology overview**

This briefing describes the regulated use of the technology for the indication specified, in the setting described, and with any other specific equipment referred to. It is the responsibility of healthcare professionals to check the regulatory status of any intended use of the technology in other indications and settings.

**About the technology**

**CE marking**

The BCM – Body Composition Monitor was originally CE-marked to Fresenius Medical Care as a Class IIa medical device in 2003; the CE mark was last updated in June 2011.

**Description**

The BCM – Body Composition Monitor uses bioimpedance spectroscopy to estimate the amount of fluid in a person's body. This information is used to help estimate a person's target weight when having haemodialysis (HD) or peritoneal dialysis (PD) for chronic kidney disease (CKD).

The BCM – Body Composition Monitor transmits alternating electric currents through a person's body and measures impedance (how easily the current flows). It is connected to the person being monitored by adhesive electrodes and an electrode connecting cable.

For monitoring, the person lies down, with their arms held slightly away from the body and legs apart. The person should have removed all metallic jewellery and the clinician checks that the person is not in contact with any metallic objects or surfaces. Two electrodes are connected to the back of 1 hand – 1 electrode is placed just above the knuckles and the other across the front of the wrist joint. A further 2 electrodes are attached to the person's foot on the same side of the body, with 1 electrode just above the toe joints at the top of the foot and the second across the front of the ankle joint. Hydrogel is applied to each electrode to help conduct the current. A 2 minute waiting period must be allowed after connecting the electrodes to the person's skin, so that the body fluid adjusts to the person being horizontal and the hydrogel adjusts to the warmth and moisture of the skin. Failure to wait the 2 minutes may result in inaccurate measurement.
The electrodes are then connected to the device using a cable. The electrodes and ends of the connecting cables are colour-coded red and black, to ensure that the correct connections are made. Data on the person's height, weight, age and sex characteristics are entered into the device using the input buttons. The BCM – Body Composition Monitor passes a small alternating current at 50 different frequencies between 5 and 1000 kHz through the body, measuring the impedance between the person's hand and foot, to give relative impedance values for each frequency. The person does not experience any unpleasant sensations while having the test.

The device uses integrated software to calculate a person's body fluid volume, based on the relative impedances and the person's entered characteristics. The software consists of 2 predictive mathematical models called the volume model and the body composition model. The degree of fluid overload (FO) the person has is reported in litres, and this value is subtracted from the person's current weight (in kilograms) to give an estimate of their normally hydrated weight. If the person is dehydrated, they will have a negative FO. In this case, the corresponding positive FO number will be added to their current weight to give their normal hydration weight.

The BCM – Body Composition Monitor also calculates other clinically relevant factors, such as urea distribution volume, total body water, extracellular water, intracellular water, lean tissue index, fat tissue index and body cell mass.

The reading takes around 10 seconds and the results are shown on the device's display panel in about 2 minutes. A second measurement should always be taken because inconsistent readings could indicate a technical problem, such as an inappropriate current pathway being formed by contact between the arms and body, or contact with a metal foot rest. Both of these can cause errors in the measured impedance properties of the body.

As well as being displayed on the inbuilt screen, the person's data can be saved onto a credit card-sized PatientCard, an external data storage device. This happens automatically when a PatientCard is put in the slot on the BCM – Body Composition Monitor. Test results can be transferred from the PatientCard to a computer using a card reader. A healthcare professional can then use the Fluid Management Tool (FMT) software to review the results. This software is only available for Windows operating systems. The FMT software allows for data management and additional analysis tools, such as generating graphs and tables of results.

The PatientCard stores 1 measurement at a time, until it is personalised with the person's height, date of birth (used to calculate age) and sex using the FMT and card reader. This then removes the need to enter these data when taking a reading. Once personalised, the card can hold up to 20 measurements for that person. Additionally, the BCM – Body Composition Monitor is
compatible with the data storage card supplied with the 5008 CorDiax HD machine, available from
the same manufacturer, which stores 3 measurements per person.

The BCM – Body Composition Monitor measures 16.9 × 11.2 × 27.2 cm (width × height × depth)
and weighs 2 kg. It has an internal rechargeable battery, which allows the device to be operated
without connection to mains power. The manufacturer estimates that the monitor can be used for
up to 5 hours when the battery is fully charged.

The BCM – Body Composition Monitor is supplied with a test box, which checks that the device and
the connecting cables are functioning properly. This test should be run every month. The electrode
connecting cable should be cleaned using a soft cloth and disinfectant after each use. The monitor
should be cleaned with disinfectant every day.

The manufacturer states that measurements can be taken for a person having PD with either a full
or empty peritoneal cavity, because the device detects fluid in the body tissue and blood almost
exclusively, rather than in the peritoneum. However, for the measurements of body composition to
be accurate, the person's weight with an empty cavity should be entered into the device. If
post-dialysis fluid status is measured for people having outpatient HD, the manufacturer
recommends that the reading should be taken no less than 30 minutes after dialysis or longer if
possible, to let the fluids in the body redistribute. The reading must be taken before the person
changes their fluid status by drinking or sweating, to be able to interpret the results as
'post-dialysis'.

The device can be used for people with amputations. If the electrodes can be connected to a hand
and foot on the same side of the body, the BCM – Body Composition Monitor will produce an
estimate of FO. This estimate must be manually converted to take into account the amputation,
using conversion tables provided by the manufacturer. The manufacturer states that a planned
update of the device will automate this conversion within the device software. If it is not possible
for the electrodes to be placed on the hand or foot on the same side of the body because of multiple
open wounds or amputations, alternative electrode configurations, such as hand-to-hand or right
hand-to-left foot measurements can be used. In these cases, the manufacturer does not
recommend direct use of the FO value predicted by the BCM – Body Composition Monitor, but
states that trend analysis over time can be used. Keane and Lindley (2015) found a downward bias
of −0.1 litres (95% confidence interval [CI] −1.6 to 1.4 litres) on FO for hand-to-hand measures
compared with hand-to-foot measures. They concluded that hand-to-hand measures give a
reasonable estimate of hydration status when hand-to-foot measures on the same side of the body
are not possible.
Setting and intended use

The BCM – Body Composition Monitor is intended for use in measuring the degree of FO in people having either HD or PD. For HD, measurements are usually made before dialysis but they can also be taken post-dialysis or in-between treatments. Measurements should not be taken during HD. The readings are translated into estimates of a person's normally hydrated weight. This is used in deciding the person's target weight, together with many other physical indicators, such as symptoms, concomitant conditions, current medication, residual kidney function and blood pressure. These other indicators are the same as those that inform the setting of target weight by clinical judgement in current NHS practice. The BCM – Body Composition Monitor gives an objective check that clinical symptoms are not being misinterpreted.

The BCM – Body Composition Monitor can be used in dialysis centres, hospitals, medical practices or at home. The rechargeable battery and carrying handle mean that it can be moved to the location where it is needed. It should not be used in intensive care units because there could be interference between it and other connected monitoring devices. In addition, a person's weight may not be accurately known and drug combinations used in this setting may change the natural distribution of fluids in the body.

The manufacturer of the BCM – Body Composition Monitor reports that there are no known contraindications for the device; however, it should not be used in people with a unipolar pacemaker if the threshold sensitivity (how sensitive the pacemaker is to electrical signals produced by the heart) is very low.

The device can be used for children. A validation of its measurement of FO in a cohort of children aged between 2 and 17 years has been presented at an international conference on paediatric nephrology, but this has not yet appeared in a peer-reviewed journal.

The BCM – Body Composition Monitor can also be used to evaluate fluid status in people at every stage of CKD, although its use outside dialysis treatment is beyond the scope of this briefing.

Current NHS options

In current UK practice, a person's target weight is established by clinical judgement and a trial-and-error approach. Clinicians make judgements about a person's FO level using many physical indicators, such as symptoms, concomitant conditions, current medication, residual kidney function and blood pressure. If a person shows signs usually associated with being over-hydrated, such as oedema and high blood pressure, their target weight is reduced incrementally, until these signs disappear. Similarly, if a person shows signs usually associated with being under-hydrated,
such as low blood pressure, cramps, dizziness and tiredness, their target weight is increased incrementally until these signs disappear. Changes in a person's target weight may influence both the frequency and duration of dialysis. When it is believed that the person's target weight has been established, the healthcare team give advice to maintain this weight as closely as possible between dialysis sessions through a combination of diet and fluid intake (Oxford University Hospitals 2015). Establishing and maintaining a suitable target weight is complicated because symptoms are non-specific, possibly relate to factors other than fluid status, or may not be present at all (NHS Technology Adoption Centre 2011). In addition, if a person's weight changes naturally through the accumulation or loss of muscle, fat or bone density, the target weight will need to be adjusted accordingly (North Bristol NHS Trust 2008).

NICE is aware of the following CE-marked devices that appear to have a similar function to the BCM – Body Composition Monitor:

- Bodystat 1500 (Bodystat)
- Quadscan 4000 (Bodystat)
- MC980 (Tanita)
- BIA101 (Akern)
- Bioscan (Maltron)
- Inbody720 (Inbody).

The MultiScan 5000 (Bodystat) has internal software that is capable of producing an estimate of a person's FO. The other devices are not specifically designed for or validated in CKD patients, and cannot be used to directly calculate FO.

**Costs and use of the technology**

The list price for the BCM – Body Composition Monitor package is £5750, excluding VAT. This package contains:

- the Body Composition Monitor
- a test box for running monthly tests
- 40 disposable electrodes, sufficient for 10 measurements
• a cable for connecting the 4 electrodes to the monitor

• 10 PatientCards

• an external PatientCard reader for transferring data to a computer

• a charging cable, used to connect the device to mains electricity and to charge the internal battery

• a copy of the Fluid Management Tool software, which can be installed on any number of PCs.

Further consumable elements can be purchased:

• 40 disposable electrodes – £30

• 10 PatientCards – £62.80.

The manufacturer offers 2 contracts for maintaining a single machine:

• planned maintenance for 1 year – £250

• planned maintenance including parts and labour for 1 year – £600.

The technology does not have a specified lifespan. Currently, the manufacturer will upgrade older versions of the device upon request, as key modifications occur. Each upgrade is invoiced individually.

The average reading using the BCM – Body Composition Monitor is expected to take around 5–10 minutes, including the time taken to connect the person to the device, run the integrated software and get the results. Some training is needed to use the device. The manufacturer gives free initial training, which takes place over 2 days. This is intended for key care-team members who can then train their colleagues. The manufacturer also offers periodic assistance if needed, which is provided free of charge.

The Leeds Teaching Hospitals NHS Trust has prepared a standard operating procedure document (SOP) for using the BCM – Body Composition Monitor in UK clinical practice, which can be found as an appendix to the NHS Technology Adoption Centre report (2011).

The manufacturer states that the BCM – Body Composition Monitor should be tested once a month by a healthcare professional using the supplied test box. This ensures the device and the connecting cables are operating as intended. The procedure takes around 2 minutes.
The BCM – Body Composition Monitor is not intended to replace using clinical judgement in the diagnosis and treatment of fluid imbalance, but to be an objective measure to complement clinical judgement.

There is no limit to the frequency with which people can be tested with the BCM – Body Composition Monitor. The manufacturer recommends that readings are taken 1 to 3 times per week over a period of 1 month for people new to dialysis, to establish a reference dataset of readings. Subsequently, people who are stable on dialysis should be monitored at least every 3 to 4 months.

According to the NHS Technology Adoption Centre report (2011), the Leeds Teaching Hospital NHS Trust’s dialysis centre started using the BCM – Body Composition Monitor when people first began treatment or if requested by a person having dialysis or by the clinic staff, but with the intention that monitoring would be done every 3 to 4 months even when people have no fluid related symptoms. Typical reasons for requesting a measurement with the BCM – Body Composition Monitor are concerns over blood pressure, the presence of fluid imbalance symptoms, or the person being monitored feeling they have gained or lost weight.

**Likely place in therapy**

The BCM – Body Composition Monitor would be used to provide additional objective measurements of fluid status when setting a person's target weight for either HD or PD.

**Specialist commentator comments**

All 4 of the specialist commentators have experience of using the BCM – Body Composition Monitor; 3 in people having HD and 2 in people having PD. Each stated that the device is useful in helping to manage the fluid status of people having dialysis.

Three of the specialist commentators noted the objectivity of the device, compared with clinical symptoms that are often absent or unspecific. However, all 4 specialist commentators highlighted that the device does not provide a treatment decision and should be used alongside clinical judgement. Two commentators said that the BCM – Body Composition Monitor is well liked by people having dialysis, because it provides an objective, numerical figure. Further, it has improved communication between dialysis users and staff about fluid gain between treatments. Another commentator felt that sharing the results with the person being monitored can provide motivation to better control salt and fluid intake, an important determinant of whether target weight is achieved.
One commentator said that the BCM – Body Composition Monitor was the only bioimpedance device trialled at their centre that has been accepted into routine use by staff. They attributed this to the device being battery powered and easy to clean, making it suitable for bedside use. Additionally, it gives a measurement of over-hydration in litres and an estimate of a person's normally hydrated weight. One of the commentators highlighted that the readings may not be accurate if a person has characteristics, such as extreme obesity, that were not well represented in the sample of people used to populate the underlying volume and body composition models. Another commentator also noted the potential for inaccuracy but stated that if the device is used consistently then the inaccuracy should remain constant.

The commentators identified several subgroups of people for whom the BCM – Body Composition Monitor may be particularly useful. One commentator said that they use the BCM – Body Composition Monitor in paediatrics, after having validated it in healthy children, and that it is helpful when tracking changes in real weight while the child is growing. Another 2 commentators indicated that they felt the technology was useful in young people and people who are overweight, who were more likely to tolerate greater dehydration without showing symptoms than other groups. The same 2 commentaries also highlighted the BCM – Body Composition Monitor's usefulness in older people, in whom the thresholds between being over- and under-hydrated are particularly close.

One specialist noted that because the monitor can be operated by junior staff it can be used frequently, collecting a useful database of results for each person being monitored.

All 4 commentators agreed that the BCM – Body Composition Monitor is useful because high blood pressure is not always linked to over-hydration, making it a difficult symptom to interpret. One specialist commentator said that the biggest change in practice as a result of using the BCM – Body Composition Monitor is in managing hypertension in people having dialysis. Previously, consultants would typically reduce the target weight of a person with high blood pressure. In their centre, it is now more common to use a BCM – Body Composition Monitor measurement to check whether high blood pressure is fluid related.

Two commentators said that although they have not audited the use of the BCM – Body Composition Monitor in their hospitals, they thought that the improved target weights have reduced the frequency of some symptoms. In addition, they thought that admissions due to FO and the number of X-rays to check for pulmonary oedema have been reduced, leading to reduced costs.

One specialist commentator mentioned that dieticians use the BCM – Body Composition Monitor to monitor changes in lean and adipose tissue in people on dialysis while having nutritional
interventions. Two commentators said that in addition to the BCM – Body Composition Monitor measurements, dietary advice should also be given to people having dialysis.

**Equality considerations**

NICE is committed to promoting equality and eliminating unlawful discrimination. In producing guidance, NICE aims to comply fully with all legal obligations to:

- promote race and disability equality and equality of opportunity between men and women
- eliminate unlawful discrimination on grounds of race, disability, age, sex, gender reassignment, pregnancy and maternity (including women post-delivery), sexual orientation, and religion or belief (these are protected characteristics under the Equality Act 2010).

The incidence of CKD and the need for dialysis increases with age (NICE guideline on peritoneal dialysis) as does the presence of fluid overload in those people having dialysis (Guo et al. 2013). African-Caribbean and south Asian family origin minority groups are 3–5 times more likely to develop kidney failure than white people (NHS Choices 2015b). The reasons for this include higher rates of high blood pressure in African or Caribbean people and higher rates of diabetes in people of south Asian family origin (NHS Choices 2015a). Age and race are protected characteristics under the Equality Act 2010.

**Patient and carer perspective**

A spokesperson from the British Kidney Association provided the following comments about the BCM – Body Composition Monitor:

- Estimation of a person's target weight using clinical judgement is difficult and the results of misestimation can be very unpleasant.
- Observations made by the clinical team and their interactions with the person having dialysis are important determinants in setting the correct target weight. These factors will continue to be important if the BCM – Body Composition Monitor is adopted.
- It is strongly recommended that the measurements from the BCM – Body Composition Monitor are shared with the person having dialysis to help them self-manage their condition.
Evidence review

Clinical and technical evidence

Regulatory bodies

A search of the Medicines and Healthcare Products Regulatory Agency website revealed no manufacturer Field Safety Notices or Medical Device Alerts for this device. No reports of adverse events were identified from a search of the US Food and Drug Administration (FDA) database: Manufacturer and User Device Facility Experience (MAUDE).

Clinical evidence

Validation of BCM – Body Composition Monitor

Wabel et al. (2009) reviewed studies comparing the BCM – Body Composition Monitor with clinical assessment or ultrafiltration volume, and summarised the results. The authors concluded that there was good agreement with these alternative measures of fluid overload (FO).

No studies have validated the BCM – Body Composition Monitor in people having peritoneal dialysis (PD). The manufacturer claims that the method used is valid across both forms of dialysis.

Prevalence of fluid overload and impacts for survival

The BCM – Body Composition Monitor has been used to establish the prevalence of fluid imbalance in dialysis users. A small case study from the HD unit in Skipton reported that 22 out of 31 (71%) people having haemodialysis (HD), who were tested with the BCM – Body Composition Monitor, had their target weight adjusted after the measurement. Fourteen people (45.2%) had their target weight increased. The remainder (8 people, 25.8%) had their target weight decreased (NHS Technology Adoption Centre 2011). The change in target weight, as a result of measurements with the BCM – Body Composition Monitor, shows that people were not at the fluid level their clinical team had expected.

A Portuguese study using the BCM – Body Composition Monitor found that 6.7% of people having PD were over-hydrated, as defined by at least 15% more body fluid than would be expected with normal hydration (Aguiar et al. 2015).

The long-term survival of people having renal replacement therapy (RRT) is lower than in the general population. A study of people in the UK (based on findings from the UK Renal Registry) who
started having RRT in 2000 showed that only 45% were alive at 5 years and 28% were alive at 10 years. The leading cause of death identified in a separate group of people who started having RRT in 2010 was cardiac disease (21%), although there was no underlying analysis indicating to what extent suboptimal fluid status contributed towards these deaths (The Renal Association 2012). Three studies (Wizemann et al. 2009; Chazot et al. 2012; O'Lone et al. 2014) using the BCM – Body Composition Monitor have shown that severely over-hydrated people having RRT have shorter survival times than those with good fluid control, compounding the already lowered life expectancy. For HD, the mortality risk in over-hydrated people was between 2.1 and 3.4 times higher than in people with normal hydration (Wizemann et al. 2009; Chazot et al. 2012). In PD the risk was 1.8 times higher (O'Lone et al. 2014).

**Using the BCM – Body Composition Monitor to guide fluid management**

Twenty studies were identified, 9 of which were excluded for the following reasons: 1 because it was a study protocol; 6 did not use an appropriate comparator; 1 appeared to sample the same people as a later study and 1 had a population outside the scope of the briefing. Of the remaining 11 studies, 5 representing the best quality evidence were selected (based on study design, number of patients and relevant outcome measures) and are summarised in this briefing.

The Canadian Agency for Drugs and Technology in Health reviewed bioimpedance devices in 2014, focusing largely upon the BCM – Body Composition Monitor. Five studies in 371 patients were assessed including the reports by Hur et al. (2013), Luo et al. (2011) and Moissl et al. (2013) summarised in this briefing. The report concluded that there was limited evidence linking the use of the BCM – Body Composition Monitor to better patient outcomes such as decreased blood pressure, reduced FO and decreased left ventricular mass index.

Four of the papers summarised in this briefing (Hur et al. 2013; Luo et al. 2011; Onofriescu et al. 2014; Ponce et al. 2014) used a randomised controlled trial (RCT) design. The remaining paper (Moissl et al. 2013) was a prospective interventional trial. Four of the papers (Hur et al. 2013; Moissl et al. 2013; Onofriescu et al. 2014; Ponce et al. 2014) included people having HD only and 1 of the studies included people having PD only (Luo et al. 2011). All 5 studies compared clinical judgement to the BCM – Body Composition Monitor, either alone or in conjunction with clinical judgement. Data tables for all summarised studies are presented in the appendix.

Hur et al. (2013) did a prospective RCT to investigate whether objective measurement of FO with the BCM – Body Composition Monitor is helpful in optimising fluid status. Eligible people, aged 18 years and older, who had HD 3 times a week for at least 3 months, were recruited from 2 dialysis centres in Turkey. Patients were randomised into 2 groups. In the intervention group (n=78), FO
information from the BCM – Body Composition Monitor was given to the treating physicians and used to adjust fluid removal during dialysis. In the control group (n=78), FO information was not given and fluid removal during dialysis was determined according to usual clinical practice. Usual clinical practice consisted of clinically estimating target weight and a chest radiograph to calculate cardiothoracic index. FO was assessed twice a month in the intervention group and once every 3 months in the control group during a 1 year follow-up. The results showed that time-averaged fluid overload (TAFO) significantly decreased in the intervention group compared with the control group (mean difference between groups: −0.5; 95% confidence interval [CI] −0.8 to −0.2; p=0.001). Left ventricular mass index (LVMI) is used as a measure of the extent of hypertrophy and is an indicator of myocardial health. LVMI decreased significantly in the intervention group compared with the control group (mean difference between groups: −10.2; 95% CI −19.2 to −1.17; p=0.04). Pre- and post-dialysis systolic and diastolic blood pressure (BP; mmHg) all significantly decreased in the intervention group compared with the control group: pre-dialysis systolic BP (mean difference between groups: −4.5; 95% CI −8.9 to 0.1; p=0.04; these figures may have been misreported in the paper), pre-dialysis diastolic BP (mean difference between groups: −2.6; 95% CI −4.8 to −0.3; p=0.02), post-dialysis systolic BP (mean difference between groups: −6.6; 95% CI −11.1 to −1.9; p=0.005), post-dialysis diastolic BP (mean difference between groups: −3.7; 95% CI −6.0 to −1.4; p=0.002). Tables 2 and 3 show the summary and results of the study.

Onofriescu et al. (2014) conducted a RCT to compare health outcomes between people having HD who had fluid removal guided by the BCM – Body Composition Monitor or clinical judgement. People were recruited from a Romanian HD centre and randomised into 2 groups. In the intervention group (n=62), the BCM – Body Composition Monitor results were disclosed to clinicians. In the control group (n=69), the BCM – Body Composition Monitor results were not disclosed to clinicians. People in both groups had BCM – Body Composition Monitor measurements every 3 months for 2.5 years. It is not reported whether the BCM – Body Composition Monitor results were disclosed to the people having dialysis in either group. A final follow-up measurement was taken at 3.5 years. The results of the study showed that from baseline to the end of the intervention (2.5 years), the number of deaths was significantly lower in the intervention group (1 in the BCM – Body Composition Monitor group compared with 8 in the clinical judgement group; log rank test p=0.008); improvement in arterial stiffness (measured with pulse wave velocity [m/s]) was significantly higher in the intervention group (−1.50 compared with 1.2; mean difference in change: −2.78; 95% CI −3.75 to 1.80; p<0.001; these figures may have been misreported in the paper); and relative FO improvement (measured with relative fluid overload [%]) was significantly higher in the intervention group (mean difference in change: −2.99; 95% CI −5.00 to −0.89; p=0.05). The change in systolic blood pressure (mmHg) was not statistically different in the intervention group (−6.5 compared with −4; mean difference in change: −2.43; 95% CI −7.70 to 2.84; p=0.4). The change in number of hypotension cramps was not statistically significant between
groups (number of events not reported, p=0.06). Tables 4 and 5 give the summary and results of the study.

Ponce et al. (2014) carried out an RCT that aimed to compare the performance of the BCM – Body Composition Monitor and conventional clinical judgement in assessing the hydration status of people using HD who were over-hydrated and determining their ideal weight. All adults attending 23 participating centres in Portugal were considered for inclusion with follow-up conducted on 189 people determined to be over-hydrated using the BCM – Body Composition Monitor at baseline. Dialysis centres were randomly divided into intervention centres, where staff were given the BCM – Body Composition Monitor results (n=101), or 'blinded' centres, where measurements from the BCM – Body Composition Monitor were not given to staff and hydration status was determined by clinical judgement (n=88). Each person was followed for 12 months during which time monthly assessments were completed. Although the use of the BCM – Body Composition Monitor reduced over-hydration (differences between groups at 12 months: 0.42 litres; 95% CI −0.02 to −0.86; p=0.06), blood pressure, the number of hypotensive events and hospitalisations relative to the clinical judgement group, none of these differences were significant (p>0.05). Tables 6 and 7 give the summary and results of the study.

Moissl et al. (2013) did a prospective interventional trial to assess the feasibility and clinical consequences of active fluid management guided by BCM – Body Composition Monitor in HD patients. Fifty-six people were recruited from 2 dialysis centres in Spain. All were aged over 18 years and had in-centre dialysis 3 times a week for at least 6 months before the study start. Follow-up was completed for 55 people over the 3 month study period. Pre-dialysis FO was measured weekly with the BCM – Body Composition Monitor to calculate time-averaged fluid overload (TAFO). The aim was to bring the TAFO of all patients into an optimal fluid status target range of 0.5±0.75 litres within the first month and maintain optimal status until study end. For analysis, patients were grouped according to their baseline hydration status. The results showed that TAFO significantly decreased from pre- to post-intervention in the fluid-overloaded group (n=17; −1.20±1.32 litres; p<0.01), remained unchanged in the normovolaemic (a normal volume of blood in the body) group (n=26; p=0.59), and significantly increased in the dehydrated group (n=12) by 0.59±0.76 litres; p=0.02). Post-intervention, 42 of 55 (76%) patients were either on target or closer to target compared with baseline. Differences in symptom rates between dialysis sessions were not significant (number of events not reported, p>0.05). Tables 8 and 9 give the summary and results of the study.

Luo et al. (2011) tested whether sharing information from the BCM – Body Composition Monitor with people having dialysis and dialysis staff helps in controlling over-hydration compared with clinical evaluation of fluid status alone. The study was an RCT with recruitment from patients
attending a single Chinese treatment centre. All 165 people enrolled were having continuous PD, were over 18 years at the start of the trial and had been having PD for a minimum of 3 months. People were randomly allocated to 2 groups. In the BCM – Body Composition Monitor group, the people and their nurses were told the FO values given by the BCM – Body Composition Monitor. In the control group, these measurements were not revealed and fluid volume was measured using the centre's standard protocols. The details of the protocols were not reported. The follow-up period was 3 months with data observations taken at 6 and 12 weeks. Over-hydration status reduced in the BCM – Body Composition Monitor group, a change that was significantly different from baseline at 12 weeks (difference at 12 weeks: −0.58 litres; p<0.05). Over-hydration status increased in the clinical management only group, and again this was significantly different to baseline at 12 weeks (difference at 12 weeks: 0.32 litres; p<0.05). At final follow-up, over-hydration was significantly lower in the BCM – Body Composition Monitor group compared with the clinical judgement group (between group difference at 12 weeks: 0.80 litres; p<0.05). Tables 10 and 11 give the summary and results of the study.

Recent and ongoing studies

Seven ongoing or in-development trials using the BCM – Body Composition Monitor for fluid status measurement during dialysis were identified in the preparation of this briefing.

- **Body Composition Monitor (BCM) guided fluid management in maintenance haemodialysis (MHD) patients (BOCOMO) (NCT01509937)**. The expected primary completion date for the study is April 2016.

- **Control of fluid balance guided by body composition monitoring in patients on peritoneal dialysis (COMPASS) (NCT01887262)**. The expected primary completion date for the study was May 2015, although the study was still listed as recruiting in July 2015.

- **Extravascular lung water monitoring by combined ultrasound and bioimpedance as a guide for treatment in haemodialysis patients (NCT01815762)**. The primary completion date for the study is October 2015.

- **The effects of haemodialysis session on vascular stiffness (PWV/CP/HD) (NCT02443376)**. The expected primary completion date for the study was June 2015, although the study was still listed as recruiting in July 2015.

- **Changes in volumetric hemodynamic parameters induced by fluid removal on hemodialysis (CI/HD) (NCT02485782)**. The expected primary completion date for the study is July 2015.
Mobilising lower limb fluid for hemodynamic stability in haemodialysis (NCT02450474). The expected primary completion date for the study is January 2016.

Initiative for patient outcomes in dialysis - peritoneal dialysis (PD) (IPOD-PD Study) (NCT01285726). The expected primary completion date for the study is December 2015.

A further 3 trials were identified in clinical areas outside fluid management for dialysis. The topics of the other identified trials were people having intravenous fluid therapy (n=1), general anaesthetic (n=1) and evaluating the metabolic profile of people after a myocardial infarction (n=1).

Costs and resource consequences

The BCM – Body Composition Monitor is a standalone device that can be used with the clinical evaluation of fluid status for people having dialysis. Evaluations using the BCM – Body Composition Monitor could be done when people attend the dialysis clinics or during home visits by centre staff.

A complete evaluation using the BCM – Body Composition Monitor is expected to take between 5 and 10 minutes. The BCM – Body Composition Monitor is a simple test to conduct, but the results need a high degree of clinical knowledge to interpret. The same level of skill is needed for setting target weight with or without the use of the BCM – Body Composition Monitor. The expertise of the clinician interpreting results is particularly important in people with amputations, heart failure, chronic oedema or on multiple medications. However, once an optimal target weight is established, that hydration status is easier to monitor and maintain with the BCM – Body Composition Monitor, even if the person's weight changes. In the clinical setting, efficient use of the device may involve having lower grade or less experienced staff collect data that is then interpreted by more senior and experienced staff (NHS Technology Adoption Centre 2011).

If effective, the BCM – Body Composition Monitor may lead to overall cost savings. These may result from reductions in heart disease, hypotensive events, further decline in kidney function and the use of prescription blood pressure medication (NHS Technology Adoption Centre 2011).

A US study of 176,790 people having HD, followed for an average of 2 years, found that 5.5% of people had a fluid overload-related episode that led to a hospital stay of 3 or fewer days. A further 1.7% had a stay of between 3 and 4 days and 1.1% had a stay of greater than 4 days. The definition used for an FO event was an admission coded as FO, heart failure or pulmonary oedema using ICD-9-CM scores with dialysis done on the day of admission or on the following day (Arneson et al. 2010). It is not clear if this definition has sufficient specificity to eliminate episodes not directly related to fluid imbalance.
None of the 5 clinical studies summarised in this briefing measured resource use.

A report on the technology by NHS Technology Adoption Centre (2011) noted that the cost savings that could be experienced by an NHS trust through adoption of the technology are variable and dependent upon a number of factors, but did not elaborate further.

**Strengths and limitations of the evidence**

The BCM – Body Composition Monitor has been validated against ultrafiltration rate and clinical judgement. However, these measures are themselves imperfect, and neither should be considered a gold standard method of estimating FO. While Wabel et al. (2009) summarise evidence from several sources, in 1 case the original referenced paper could not be found and the other was only published in abstract form.

The impact that the BCM – Body Composition Monitor would have, if introduced into the NHS, is difficult to establish due to lack of high quality prevalence data. The presented results from the Skipton HD unit are based on a small sample. It is uncertain whether the Portuguese results from Aguiar et al. (2015) can be generalised to the UK, and the paper did not report how frequently target weight changed as a result of the over-hydrated result.

The 4 RCT studies were evaluated using the RCT QA checklist recommended by the NICE guidelines manual: [appendices B–I](https://www.nice.org.uk/guidance/MIB41). A summary is reported in table 1.

**Table 1 Levels of bias in the 4 RCTs**

<table>
<thead>
<tr>
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<tbody>
<tr>
<td>Selection bias</td>
<td>Unclear risk</td>
<td>Low risk</td>
<td>High risk</td>
<td>Unclear risk</td>
</tr>
<tr>
<td>Performance bias</td>
<td>High risk</td>
<td>Low risk</td>
<td>High risk</td>
<td>High risk</td>
</tr>
<tr>
<td>Attrition bias</td>
<td>Low risk</td>
<td>Low risk</td>
<td>High risk</td>
<td>Low risk</td>
</tr>
<tr>
<td>Detection bias</td>
<td>Low risk</td>
<td>Low risk</td>
<td>Low risk</td>
<td>High risk</td>
</tr>
</tbody>
</table>

The risk of selection bias in Hur et al. (2013) and Luo et al. (2011) was unclear. The studies did not report the randomisation method used or if allocation was concealed. Hur et al. did report baseline characteristics of the people being assessed and there was no statistically significant difference.
between groups. Luo et al. also reported that there was no difference between baseline characteristics of the 2 groups, however, no statistical test results were given. The risk of selection bias in Onofriescu et al. (2014) was assessed to be low. The method of randomisation was reported, although it was unclear if allocation was concealed, and there were no statistical differences between groups at baseline.

The risk of selection bias in Ponce et al. (2014) was assessed to be high. The method of randomisation was not provided, it was unclear if the allocation was concealed and no formal tests were used to compare baseline characteristics between study groups. There appear to be large differences in some clinically relevant characteristics between groups at the start of the study. These include gender, number of patients with coronary artery disease, number of patients who have had myocardial infarction, and number of patients with peripheral vascular disease. In addition, the patients were selected for inclusion by using the BCM – Body Composition Monitor to detect over-hydration at baseline. Therefore, there is a chance of bias because the study relies on the tool that is being evaluated to select patients for inclusion.

Three studies (Hur et al. 2013, Luo et al. 2011 and Ponce et al. 2014) were assessed as having a high risk of performance bias. Hur et al. did not report if dialysis users were blind to treatment allocation, although this seems unlikely because the 2 groups had different frequencies of measurement. Individuals administering care were not blinded to treatment allocation and the authors noted that the evidence suggested that extra care was given to those in the control group. Luo et al. reported that people having dialysis and clinicians were not blinded, which may have introduced performance bias. Ponce et al. reported that patients were blinded to treatment allocation but physicians were not. However, because randomisation allocation was by centre rather than patient, there may have been systematic differences between groups in the care that was given.

The study by Onofriescu et al. (2014) was assessed as having a low risk of performance bias because each group had the same intervention and patients were blinded to treatment, although clinicians were not blinded to treatment allocation due to necessity, because it was difficult to mask the intervention for the caregivers.

The Hur et al. (2013), Luo et al. (2011) and Onofriescu et al. (2014) studies were assessed as having a low risk of attrition bias. All 3 studies reported that patients were followed up for an equal length of time. There do not appear to be important or significant differences between groups for those people who did and did not complete treatment. Hur et al. also reported no difference between people who completed the study and those people who did not. All 3 studies had a low number of drop-outs.
Ponce et al. (2014) was assessed as having a high risk of attrition bias. There was some discrepancy between when patients had monitoring, a fairly high proportion were lost to follow-up (28.8% in the BCM – Body Composition Monitor group and 47.7% in the blinded group) and the paper does not state what happened to those who left the study early.

The studies by Hur et al. (2013), Onofriescu et al. (2014) and Ponce et al. (2014) were assessed as having a low risk of detection bias. All 3 studies had an appropriate length of follow-up, long enough to accurately capture most of the defined outcomes. All studies would benefit from longer follow-up to capture mortality. However, this is a common issue and due to practicality cannot always be avoided. All 3 studies used precise definitions of outcomes, and valid and reliable measures were used to determine the outcomes. However, the Onofriescu et al. and Ponce et al. studies could have benefitted from longer follow-up when measuring long-term outcomes, such as mortality. Although it was unclear if the investigators were kept blind to participants' exposure to the intervention and to other confounding factors, most primary measurements taken were objective and, therefore, are unlikely to be biased.

The study by Moissl et al. (2013) was assessed using the CASP cohort studies checklist (CASP UK 2013). The study recruited the cohort in an acceptable way using eligibility criteria; however, no calculation was used to determine sample size. Because patients with comorbidities were excluded, this limits the generalisability of the results. Details of measurement for all outcomes were not provided, although most measures were objective and were unlikely to be biased. Where detail was given, it showed that efforts were made to minimise bias. The study has a fairly short follow-up and the authors acknowledge that longer follow-up may have been informative.

Overall, the quality of the evidence was poor. Only 1 of the reviewed RCTs (Onofriescu et al. 2014) did not have a high risk of bias in at least 1 of the evaluated domains. The cohort study (Moissl et al. 2013) appeared reasonably well conducted, but ranks less highly in the hierarchy of evidence than an RCT because there is no control group.

None of the included studies were done in the UK. Onofriescu et al. (2014), Ponce at al. (2014) and Mossil et al. (2013) appear to have used the BCM – Body Composition Monitor to set target weights in isolation, rather than integrating the readings into wider considerations. All of the included studies used the primary outcomes FO or TAFO. Reductions in these values cannot be interpreted as movements towards the target weight, as set by clinical judgement with or without the BCM – Body Composition. Given limited reporting on standard care and how clinical management was applied, it is uncertain whether these results can easily be generalised to a UK context.
Relevance to NICE guidance programmes

NICE has issued the following guidance:

- **Chronic kidney disease** (2014) NICE guideline CG182. Date for review: June 2017

- **Renal replacement therapy services** (2014) NICE quality standard 72

- **Peritoneal dialysis** (2011) NICE guideline CG125. Date for review: June 2015

- **Chronic kidney disease** (2011) NICE quality standard 5

- **Guidance on home compared with hospital haemodialysis for patients with end-stage renal failure** (2002) NICE technology appraisal guidance 48

References


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CASP UK (2013) CASP cohort study checklist [online; accessed 5 July 2015]


Guy's and St Thomas' NHS Foundation Trust (2012) *A guide to living with kidney failure* [online; accessed 10 July 2015]


mykidney (2015) Choosing the treatment option that's right for you. APD and CAPD [maintained by Guy's and St Thomas' NHS Foundation Trust and King's College Hospital NHS Foundation Trust] [online; accessed 13 August 2015]

NHS Choices (2015a) *Chronic kidney disease* [online; accessed 3 July 2015]

NHS Choices (2015b) *Black and south Asian kidney health* [online; accessed 6 July 2015]

NHS Choices (2015c) *Dialysis* [online; 8 July 2015]

NHS Technology Adoption Centre (2011) *Assessment of fluid status using Body Composition Monitoring (BCM) Implementation Pack* [online; accessed 5 July 2015]
North Bristol NHS Trust (2008) Richard Bright Renal Unit – Introduction to care for people receiving dialysis [online; accessed 13 August 2015]


Ontario Renal Network (2015) Peritoneal dialysis manual [online; accessed 3 August 2015]


Ozkahya M, Ok E, Cirit M et al. (1998) Regression of left ventricular hypertrophy in haemodialysis patients by ultrafiltration and reduced salt intake without antihypertensive drugs. Nephrology Dialysis Transplantation 13:1489–93


Queen Elizabeth Hospital Birmingham (2013) Conservative kidney management [online; accessed 13 August 2015]


The Renal Association (2013) Haemodialysis dose, frequency and duration (Guidelines 5.1 – 5.10) [online; accessed 17 August 2015]


Search strategy and evidence selection

Search strategy

The search strategy was designed to identify evidence on the clinical and cost effectiveness of the Fresenius Body Composition Monitor (BCM) for use in people with chronic kidney disease (CKD) having dialysis.

The strategy was developed for MEDLINE (Ovid interface). The strategy was devised using a combination of subject indexing terms and free text search terms in the title, abstract and keyword heading word fields. The search terms were identified through discussion within the research team, scanning background literature, browsing database thesauri and use of the PubMed PubReMiner tool. The strategy reflected the nature of the MIB assessments as rapid evidence reviews.

The main structure of the search strategy comprised 2 concepts:

1) Dialysis

2) BCM.

The search concepts were combined as follows: Dialysis AND BCM.

Terms for the BCM concept focused on the key technology used by the device – bioimpedance spectroscopy.

The strategy excluded non-English language publications. Animal studies were also excluded using a standard algorithm. No additional filters for study design were applied. Results were limited to studies published from 2007 to date. This date reflected that the details of the body composition model that the Body Composition Model uses to measure fluid overload were not published in the
literature until 2007. The final MEDLINE strategy was peer-reviewed by an independent information specialist.

The MEDLINE strategy was translated appropriately for the other databases searched. The PubMed search was limited to records that were not fully indexed on MEDLINE. Conference-related records were excluded from the Embase search.

The following databases were searched:

- Cochrane Central Register of Controlled Trials (Cochrane Library, Wiley)
- Cochrane Database of Systematic Reviews (Cochrane Library, Wiley)
- Database of Abstracts of Reviews of Effects (Cochrane Library, Wiley)
- Embase (Ovid SP)
- Health Technology Assessment Database (Cochrane Library, Wiley)
- MEDLINE and MEDLINE in Process (Ovid SP)
- NHS Economic Evaluation Database (Cochrane Library, Wiley)
- PubMed.

**Evidence selection**

A total of 857 records were retrieved from the literature search. After the elimination of duplicates, 460 records remained. The title and abstracts of all 460 records were screened independently by 2 reviewers, to exclude any that met the exclusion criteria adopted for the review. The following exclusion criteria were used:

- conference abstracts
- non-English language studies
- review protocols
- sample sizes of fewer than 10 patients (for example case reports)
- articles of poor relevance against the search terms.
Disagreements between the 2 reviewers were resolved through discussion. This first sift excluded 440 papers. Full records were retrieved for the remaining 20 papers, and a second sift was carried out by the same reviewers, against the following inclusion criteria:

- Paper includes the Fresenius BCM – Body Composition Monitor
- Population of interest is adults having dialysis (hemodialysis or peritoneal dialysis). Dialysis can take place at home or a clinical setting.
- Comparator used is current clinical practice (clinical judgement used to establish target weight)
- Lists outcomes of interest, including:
  - Target weight/fluid overload, total body water, extracellular water, intracellular water
  - Short term adverse events of fluid imbalance (such as oedema, breathlessness, cramps, dizziness), blood pressure, mortality.

Papers that failed to meet these inclusion criteria, or met the previous exclusion criteria, were excluded. Again, disagreements between the 2 reviewers were resolved through discussion. One paper was excluded because it was a study protocol, 6 were excluded because they did not use the correct comparator, 1 was excluded because it appeared the same patient population was used in a later study and 1 was excluded because the study looked at the wrong patient population. Of the remaining 11 studies, the 5 studies representing the best quality evidence were selected.

All papers were assessed for methodological quality using the checklists provided within the NICE guidelines manual: appendices B–I or an adapted version of a checklist where necessary.

**Appendix**

**Contents**

**Data tables**

- **Table 2**: Overview of the Hur et al. (2013) study
- **Table 3**: Summary of results of Hur et al. (2013)
- **Table 4**: Overview of the Onofriescu et al. (2014) study
Table 2 Overview of the Hur et al. (2013) study

<table>
<thead>
<tr>
<th>Study component</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Objectives/hypotheses</td>
<td>To investigate whether objective measurement of FO with the BCM is helpful in optimising fluid status.</td>
</tr>
<tr>
<td>Study design</td>
<td>Prospective randomised controlled study.</td>
</tr>
<tr>
<td>Setting</td>
<td>156 haemodialysis patients recruited from 2 dialysis centres in Turkey. FO was assessed twice monthly in the intervention group and once every 3 months in the control group during a 1-year follow-up.</td>
</tr>
<tr>
<td>Inclusion/exclusion criteria</td>
<td>Eligible patients were older than 18 years, and on maintenance HD scheduled thrice weekly (12 hours weekly) for at least 3 months. Exclusion criteria were the presence of a pacemaker or defibrillator, artificial joints or pins, amputation, permanent or temporary catheters, being scheduled for living donor kidney transplantation, presence of serious life-limiting comorbid situations (such as malignancy, uncontrollable infection, and end-stage cardiac, pulmonary, or hepatic disease), being pregnant, or lactating.</td>
</tr>
<tr>
<td>Primary outcomes</td>
<td>Regression of LVMI, improvement in BP and improvement in left atrial volume.</td>
</tr>
</tbody>
</table>
Statistical methods

p<0.05 was considered statistically significant. Intragroup comparisons were done with paired t-test or signed rank test. Intergroup comparisons were assessed by 1-way analysis of variance or McNemar tests. A sample size power calculation was based upon previous investigations of LVMI. The required sample size was determined to be 130 patients. Considering a dropout rate of 20%, sample size was 156 patients.

Participants

156 patients were enrolled in the study (78 in each group). After study drop out, 64 remained in the intervention group (2 died, 12 had transplantation or moved centres) and 62 remained in the control group (4 died, 12 had transplantation or moved centres). There was no statistically significant difference between those who completed and did not complete the study.

Results

TAFO significantly decreased in intervention group compared with the control group. LVMI regressed significantly in intervention group compared with the control group.

Conclusions

The authors concluded that assessment of FO with bioimpedance spectroscopy provides better management of fluid status, leading to regression of LVMI, decrease in blood pressure, and improvement in arterial stiffness.

Abbreviations: BCM, BCM – Body Composition Monitor; BP, blood pressure; FO; fluid overload, LVMI; left ventricle mass index, TAFO; time-averaged fluid overload.

Table 3 Summary of results from the Hur et al. (2013) study

<table>
<thead>
<tr>
<th></th>
<th>Intervention group</th>
<th>Control group</th>
<th>Analysis</th>
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<tr>
<td>Randomised</td>
<td>n=78</td>
<td>n=78</td>
<td></td>
</tr>
<tr>
<td>Efficacy</td>
<td>n=64</td>
<td>n=62</td>
<td></td>
</tr>
<tr>
<td>Primary outcome: LVMI (g/m^2±SD)</td>
<td>Baseline: 131±36 12 months: 116±29 Change: −14.5±32.1 p=&lt;0.001</td>
<td>Baseline: 121±35 12 months: 120±30 Change: −1.3±33.2 p=0.9</td>
<td>Mean difference between groups: −10.2; 95% CI −19.2 to −1.17; p=0.04</td>
</tr>
<tr>
<td>Selected secondary outcomes:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Measure</td>
<td>Baseline (litres±SD)</td>
<td>12 months (litres±SD)</td>
<td>Change (litres±SD)</td>
</tr>
<tr>
<td>--------------------------------</td>
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</tr>
<tr>
<td><strong>FO pre-dialysis</strong></td>
<td>1.48±1.11</td>
<td>0.87±0.88</td>
<td>−0.6±0.8</td>
</tr>
<tr>
<td></td>
<td>1.19±1.34</td>
<td>1.41±1.26</td>
<td>0.2±1.2</td>
</tr>
<tr>
<td><strong>FO post-dialysis</strong></td>
<td>−0.79±1.23</td>
<td>−1.33±0.99</td>
<td>−0.5±0.9</td>
</tr>
<tr>
<td></td>
<td>−1.03±1.44</td>
<td>−1.01±1.44</td>
<td>0.0±1.3</td>
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<tr>
<td><strong>TAFO</strong></td>
<td>0.32±1.07</td>
<td>0.23±0.84</td>
<td>−0.5±0.8</td>
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<tr>
<td></td>
<td>0.12±1.31</td>
<td>0.20±1.31</td>
<td>0.1±1.2</td>
</tr>
<tr>
<td><strong>Pre-dialysis BP systolic</strong></td>
<td>129±17</td>
<td>120±19</td>
<td>−9.4±11</td>
</tr>
<tr>
<td></td>
<td>130±17</td>
<td>125±19</td>
<td>−5.0±13</td>
</tr>
<tr>
<td><strong>Pre-dialysis BP diastolic</strong></td>
<td>76±7</td>
<td>73±9</td>
<td>−3.5±5.9</td>
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<td></td>
<td>77±7</td>
<td>76±9</td>
<td>−0.9±6.4</td>
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<tr>
<td><strong>Post-dialysis BP systolic</strong></td>
<td>116±16</td>
<td>105±18</td>
<td>−11±11</td>
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<td></td>
<td>117±20</td>
<td>113±21</td>
<td>−4.8±15</td>
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</tbody>
</table>

*FO pre-dialysis* (litres±SD): Baseline: 1.48±1.11, 12 months: 0.87±0.88, Change: −0.6±0.8, p=<0.001. Mean difference between groups: −0.4; 95% CI −0.6 to −0.3; p=<0.001.

*FO post-dialysis* (litres±SD): Baseline: −0.79±1.23, 12 months: −1.33±0.99, Change: −0.5±0.9, p=<0.001. Mean difference between groups: −0.5; 95% CI −0.8 to −0.1; p=0.01.

*TAFO* (litres±SD): Baseline: 0.32±1.07, 12 months: 0.23±0.84, Change: −0.5±0.8, p=<0.001. Mean difference between groups: −0.5; 95% CI −0.8 to −0.2; p=0.001.

*Pre-dialysis BP systolic* (mmHg±SD): Baseline: 129±17, 12 months: 120±19, Change: −9.4±11, p=<0.001. Mean difference between groups: −4.5; 95% CI −8.9 to 0.1; p=0.04a.

*Pre-dialysis BP diastolic* (mmHg±SD): Baseline: 76±7, 12 months: 73±9, Change: −3.5±5.9, p=<0.001. Mean difference between groups: −2.6; 95% CI −4.8 to −0.3; p=0.02.

*Post-dialysis BP systolic* (mmHg±SD): Baseline: 116±16, 12 months: 105±18, Change: −11±11, p=<0.001. Mean difference between groups: −6.6; 95% CI −11.1 to −1.9; p=0.005.
### Table 4 Overview of the Onofriescu et al. (2014) study

<table>
<thead>
<tr>
<th>Study component</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Objectives/hypotheses</td>
<td>To compare BCM measurements with clinical methods to control a person's fluid level while having HD.</td>
</tr>
<tr>
<td>Study design</td>
<td>Randomised controlled trial.</td>
</tr>
<tr>
<td>Setting</td>
<td>People recruited from a single Romanian HD centre, who had been on HD at least 3 months. Recruitment done 2 months before July 2008. Final follow-up done for 3.5 years in December 2011, although intervention only conducted over first 2.5 years. Bioimpedance was conducted every 3 months during the intervention period.</td>
</tr>
<tr>
<td>Inclusion/exclusion criteria</td>
<td>All adults having treatment at the centre considered for inclusion. Individuals with less than 1 year life expectancy, with limb amputations, metallic joint prostheses, absence of permanent vascular access, decompensated cirrhosis, pregnancy, cardiac stent or pacemaker were excluded.</td>
</tr>
<tr>
<td>Primary outcomes</td>
<td>All-cause mortality over 2.5 years, relative arterial stiffness (measured by PWV), FO and BP.</td>
</tr>
<tr>
<td>Statistical methods</td>
<td>Mean values and frequencies of parameters were compared by analysis of variance or chi-squared test as appropriate. Differences in survival were assessed through a Kaplan–Meier plot and log rank test.</td>
</tr>
</tbody>
</table>
Participants
277 people were assessed for eligibility, with 146 excluded due to not meeting inclusion criteria (n=96) and declining to participate (n=50). 131 people were randomised to 2 groups:
BCM group, n=62
Clinical judgement group, n=69

Results
The study showed a significant difference in survival, BP and FO between the BCM group and the clinical methods group after 2.5 years of the intervention.

Conclusions
Authors concluded that the study showed improvements in both surrogate and hard endpoints after strict volume control using the BCM as a guide.

Abbreviations: BCM, BCM – Body Composition Monitor; BP, blood pressure; FO, fluid overload; HD, haemodialysis; n, number of patients; PWV, pulse wave velocity.

Table 5 Summary of results from the Onofriescu et al. (2014) study

<table>
<thead>
<tr>
<th></th>
<th>Clinical judgement group</th>
<th>BCM group</th>
<th>Analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Randomised</td>
<td>n=69</td>
<td>n=62</td>
<td></td>
</tr>
<tr>
<td>Efficacy</td>
<td>n=69</td>
<td>n=62</td>
<td>None lost to follow-up</td>
</tr>
<tr>
<td>Primary outcome:</td>
<td></td>
<td></td>
<td>Log rank test p=0.008</td>
</tr>
<tr>
<td>Survival</td>
<td>Number of deaths: 8</td>
<td>Number of deaths: 1</td>
<td></td>
</tr>
<tr>
<td></td>
<td>KM</td>
<td>KM cumulative survival: 96%</td>
<td></td>
</tr>
<tr>
<td></td>
<td>cumulative survival: 78%</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Selected secondary outcomes:
<table>
<thead>
<tr>
<th>Arterial stiffness (measured by PWV) (m/s±SD)</th>
<th>Baseline: 7.63±2.35 2.5 years: 8.88±3.23 Change: 1.25 (95% CI −0.10 to −2.38, p=0.01)</th>
<th>Baseline: 8.22±2.33 2.5 years: 6.68±1.89 Change: −1.54 (95% CI −2.80 to −0.30, p&lt;0.001)</th>
<th>Between group mean difference in change from baseline to end of intervention: −2.78 (95% CI −3.75 to 1.80, p&lt;0.001)a</th>
</tr>
</thead>
<tbody>
<tr>
<td>Relative fluid overload (%±SD)</td>
<td>Baseline: 10.30±7.70 2.5 years: 11.24±7.62 Change: 0.94 (95% CI −2.50 to 4.40, p=0.9)</td>
<td>Baseline: 9.52±7.67 2.5 years: 7.46±5.77 Change: −2.05 (95% CI −5.70 to −1.10, p=0.03)</td>
<td>Between group mean difference in change from baseline to end of intervention: −2.99 (95% CI −5.00 to −0.89, p=0.05)</td>
</tr>
<tr>
<td>Blood pressure (mm Hg±SD)</td>
<td>Baseline: 144.6±15.2 2.5 years: 140.5±11.4 Change: −4.00 (95% CI −10.83 to 2.63, p=0.4)</td>
<td>Baseline: 145.4±14.5 2.5 years: 138.9±14.7 Change: −6.5 (95% CI −13.62 to −4.53, p=0.04)</td>
<td>Between group mean difference in change from baseline to end of intervention: −2.43 (95% CI −7.7 to 2.84, p=0.4)</td>
</tr>
<tr>
<td>Mean number of hypotension cramps, per patient per year</td>
<td>6.48 (95% CI 4.59 to 7.41)</td>
<td>6 (95% CI 4.59 to 7.41)</td>
<td>p=0.6</td>
</tr>
</tbody>
</table>

Abbreviations: BCM, BCM – Body Composition Monitor; CI, confidence interval; KM, Kaplan–Meier; n, number of patients; PWV, pulse wave velocity; SD, standard deviation.

aResults presented as they appear in final paper, although they may be misreported.
Table 6 Overview of the Ponce et al. (2014) study

<table>
<thead>
<tr>
<th>Study component</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Objectives/ hypotheses</td>
<td>To compare the performance of the BCM versus conventional clinical judgement in assessing hydration status of people having HD and determining their ideal weight.</td>
</tr>
<tr>
<td>Study design</td>
<td>Randomised controlled trial.</td>
</tr>
<tr>
<td>Setting</td>
<td>People recruited from 23 Portuguese dialysis centres. The investigation was done between 2010 and 2012, although each person was only followed for 12 months, during which time they had 12 monthly assessments.</td>
</tr>
<tr>
<td>Inclusion/ exclusion criteria</td>
<td>All adults attending in participating centres were considered for inclusion. All individuals assessed were determined to be over-hydrated using the BCM monitor at baseline. All people with medical or metal implants, attached external medical devices, prosthetic joint, major amputations, pregnant women and systematic aortic valve stenosis were excluded. People were excluded if they were not treated 3 times a week or if they had a treatment duration of &lt;4 hours per session.</td>
</tr>
<tr>
<td>Primary outcomes</td>
<td>Over-hydration, blood pressure, hypotensive events, hospitalisations and death.</td>
</tr>
<tr>
<td>Statistical methods</td>
<td>Group differences at the end of study were analysed with ANCOVA. Group-specific differences between baseline and final observation were analysed using paired t-tests. Hypotensive events investigated using chi-squared test and Wilcoxon tests. Missing values of OH were imputed using the last observation carried forward principle.</td>
</tr>
</tbody>
</table>
Analysis was done on 189 people meeting inclusion criteria. In the BCM group, 29 people were withdrawn from the study because incomplete data were collected in the study time (n=17) or the person died (n=12). In the clinical judgement group, 42 people were withdrawn from the study because incomplete data were collected within the study time (n=34) or the person died (n=8). How these dropouts were factored into subsequent analysis (apart from OH) was not clear.

BCM group, n=101
Clinical judgement group, n=88

Use of the BCM monitor appears to have reduced OH, blood pressure, number of hypotensive events and hospitalisations relative to the clinical judgement group. None of these differences was significant.

The authors conclude that the BCM is a helpful tool in supporting fluid management of HD patients.

Table 7 Summary of results from the Ponce et al. (2014) study

<table>
<thead>
<tr>
<th></th>
<th>BCM group</th>
<th>Clinical judgement group</th>
<th>Analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Randomised</td>
<td>n=101</td>
<td>n=88</td>
<td></td>
</tr>
<tr>
<td>Efficacy</td>
<td>NR</td>
<td>NR</td>
<td></td>
</tr>
<tr>
<td>Primary outcome:</td>
<td></td>
<td></td>
<td>Difference between groups at 12 months: 0.42; 95% CI −0.02 to −0.86; p=0.06.</td>
</tr>
<tr>
<td>Over-hydration (litres±SD)</td>
<td>Baseline: 3.77±1.23 12 months: 2.92±1.47 Difference: p=&lt;0.0001</td>
<td>Baseline: 3.81±1.38 12 months: 3.36±1.75 Difference: p=0.0216</td>
<td></td>
</tr>
<tr>
<td>Selected secondary outcomes:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Baseline:</td>
<td>12 months:</td>
<td>12 months:</td>
</tr>
<tr>
<td>--------------------------------</td>
<td>-----------</td>
<td>------------</td>
<td>------------</td>
</tr>
<tr>
<td><strong>Pre-dialysis systolic blood</strong></td>
<td>144.8±24.1</td>
<td>134.6±27.3</td>
<td>136.5±24.7</td>
</tr>
<tr>
<td><strong>pressure (mmHg)</strong></td>
<td>68.3±14.4</td>
<td>65.4±15.8</td>
<td>64.5±16.2</td>
</tr>
<tr>
<td><strong>Pre-dialysis diastolic blood</strong></td>
<td>145.0±25.4</td>
<td>132.8±28.6</td>
<td>129.3±24.0</td>
</tr>
<tr>
<td><strong>pressure (mmHg)</strong></td>
<td>68.8±14.1</td>
<td>63.4±15.0</td>
<td>61.4±12.9</td>
</tr>
<tr>
<td><strong>Post-dialysis systolic blood</strong></td>
<td>145.9±26.8</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>pressure (mmHg)</strong></td>
<td>69.7±16.7</td>
<td>64.5±16.2</td>
<td></td>
</tr>
<tr>
<td><strong>Post-dialysis diastolic blood</strong></td>
<td>142.5±29.4</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>pressure (mmHg)</strong></td>
<td>66.1±14.2</td>
<td>61.4±12.9</td>
<td></td>
</tr>
<tr>
<td><strong>Hypotensive events</strong></td>
<td>39 events in 17 patients</td>
<td>48 events in 20 patients</td>
<td>41 events in 15 patients</td>
</tr>
<tr>
<td><strong>Hospitalisations (% of patients admitted at least once during observation)</strong></td>
<td>39.6% (40/101)</td>
<td>31.8% (28/88)</td>
<td></td>
</tr>
<tr>
<td><strong>Deaths</strong></td>
<td>11.9% (12/101)</td>
<td>9.1% (8/88)</td>
<td></td>
</tr>
</tbody>
</table>

**Abbreviations:** BCM, BCM – Body Composition Monitor; CI, confidence interval; n, number of patients; NR, not reported; OH, over-hydration; SD, standard deviation.
### Table 8 Overview of the Moissl et al. (2013) study

<table>
<thead>
<tr>
<th>Study component</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Objectives/hypotheses</td>
<td>To assess the feasibility and clinical consequences of active fluid management guided by BCM in HD (not clearly defined) patients.</td>
</tr>
<tr>
<td>Study design</td>
<td>Prospective interventional trial.</td>
</tr>
<tr>
<td>Setting</td>
<td>56 people were recruited from 2 dialysis centres in Spain (November 2011 to February 2012). Fluid status was measured weekly for a 3 month period.</td>
</tr>
<tr>
<td>Inclusion/exclusion criteria</td>
<td>Eligible people were all CKD-5 patients older than 18 years who had thrice-weekly in-centre dialysis for at least 6 months before the study start. Exclusion criteria were acute or chronic infections, severe diseases, access problems, severe intradialytic BP instabilities in the month before study start, major amputations, or pacemakers.</td>
</tr>
<tr>
<td>Primary outcomes</td>
<td>TAFO, pre dialysis FO, post dialysis FO, EWC, ICW, pre-dialysis systolic BP (mmHg), post-dialysis systolic BP (mmHg), pre-dialysis diastolic BP (mmHg), post-dialysis diastolic BP (mmHg).</td>
</tr>
<tr>
<td>Statistical methods</td>
<td>Differences between the baseline and end measurements were determined using paired t-tests. Statistical significance was deemed when p&lt;0.05.</td>
</tr>
<tr>
<td>Participants</td>
<td>56 haemodialysis patients were enrolled in the study. 54 people were followed up for the whole study period. One person died 3 weeks before study end for non-study related reasons and this person was included using intention-to-treat analysis. Another person, who changed dialysis centre after 3 weeks, was excluded from the study. Therefore analysis was based on 55 people.</td>
</tr>
<tr>
<td>Results</td>
<td>TAFO significantly decreased from pre to post intervention in the fluid-overloaded group, remained unchanged in the normovolaemic group and significantly increased in the dehydrated group. This was accompanied by a significant pre-dialysis systolic BP. The number of intradialytic symptoms did not change significantly in any of the subgroups.</td>
</tr>
<tr>
<td>Conclusions</td>
<td>The authors concluded that active fluid management provided by bioimpedance spectroscopy was associated with an improvement in overall fluid status and BP.</td>
</tr>
</tbody>
</table>
### Abbreviations

BCM, BCM – Body Composition Monitor; BP, blood pressure; CKD-5: Stage 5 chronic kidney disease; ECW, extracellular water; HD, haemodialysis; ICW, intracellular water; TAFO, time-averaged fluid overload.

### Table 9 Summary of results from the Moissl et al. (2013) study

<table>
<thead>
<tr>
<th></th>
<th>Baseline</th>
<th>3 Months</th>
<th>Analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Randomised</td>
<td>n=56</td>
<td>n=56</td>
<td></td>
</tr>
<tr>
<td>Efficacy</td>
<td>n=55</td>
<td>n=55</td>
<td></td>
</tr>
<tr>
<td><strong>Primary outcome</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TAFO (litres±SD): All patients</td>
<td>0.90±1.64</td>
<td>0.62±1.10</td>
<td>p=0.08</td>
</tr>
<tr>
<td>TAFO (litres±SD): People dehydrated at baseline (n=12)</td>
<td>−1.06±0.67</td>
<td>−0.48±0.67</td>
<td>p=0.02</td>
</tr>
<tr>
<td>TAFO (litres±SD): People normovolaemic at baseline (n=26)</td>
<td>0.58±0.42</td>
<td>0.51±0.77</td>
<td>p=0.59</td>
</tr>
<tr>
<td>TAFO (litres±SD): People overloaded at baseline (n=17)</td>
<td>2.76±1.31</td>
<td>1.57±0.99</td>
<td>p=&lt;0.01</td>
</tr>
<tr>
<td><strong>Selected secondary outcomes</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ECW (litres±SD)</td>
<td>16.7±3.0</td>
<td>16.9±2.7</td>
<td>p=0.51</td>
</tr>
<tr>
<td>ICW (litres±SD)</td>
<td>16.3±3.8</td>
<td>16.9±3.4</td>
<td>p=0.02</td>
</tr>
<tr>
<td>BPsys pre (mmHg±SD)</td>
<td>137±26</td>
<td>137±25</td>
<td>p=0.95</td>
</tr>
<tr>
<td>BPsys post (mmHg±SD)</td>
<td>135±28</td>
<td>137±26</td>
<td>p=0.37</td>
</tr>
<tr>
<td>BPdia pre (mmHg±SD)</td>
<td>63±12</td>
<td>66±14</td>
<td>p=0.04</td>
</tr>
<tr>
<td>BPdia post (mmHg±SD)</td>
<td>66±12</td>
<td>66±12</td>
<td>p=0.59</td>
</tr>
</tbody>
</table>

Abbreviations: BPsys pre, pre-dialysis systolic blood pressure; BPsys post, post-dialysis systolic blood pressure; BPdia pre, pre-dialysis diastolic blood pressure; BPdia post, post-dialysis diastolic blood pressure; ECW, extracellular water; ICW, intracellular water; IIT, intention to treat.
Table 10 Overview of the Luo et al. (2011) study

<table>
<thead>
<tr>
<th>Study component</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Objectives/hypotheses</td>
<td>To test whether sharing information from the BCM device with people having PD and dialysis staff, helps in controlling over-hydration compared with clinical evaluation of fluid status.</td>
</tr>
<tr>
<td>Study design</td>
<td>Randomised controlled trial.</td>
</tr>
<tr>
<td>Setting</td>
<td>People recruited from a single Chinese treatment centre in September 2008. Authors reported that intention was for a 6 month follow-up, but study was halted after 3 months. Data observations were taken at 6 and 12 weeks.</td>
</tr>
<tr>
<td>Inclusion/exclusion criteria</td>
<td>165 people initially enrolled having continuous PD, who were over 18 years at start of the trial. All people had been having PD for a minimum of 3 months, with no acute infection or new cardiovascular event in the past month. People who had been on 1 or 2 PD treatments a day due to economic limitation were excluded.</td>
</tr>
<tr>
<td>Primary outcomes</td>
<td>Over-hydration, extracellular water, intracellular water, systolic BP, diastolic BP.</td>
</tr>
<tr>
<td>Statistical methods</td>
<td>Between group differences were analysed through 1-way ANOVA. Within group changes over time were analysed using repeated ANOVA measurements. Statistical significance was deemed when p&lt;0.05.</td>
</tr>
<tr>
<td>Participants</td>
<td>Analysis was done on 160 people who completed follow-up period. Two people from BCM groups and 3 from the clinical management group did not complete the follow-up phase. Two people died and 3 people developed peritonitis. Reasons and numbers for within group attrition are not provided. BCM group, n=78 Clinical judgement group, n= 82.</td>
</tr>
<tr>
<td>Results</td>
<td>Both the BCM group and the clinical judgement group reduced over-hydration status, a change that was significant against baseline by 12 weeks. At final follow-up, over-hydration was significantly lower in the BCM group compared with the clinical management group.</td>
</tr>
</tbody>
</table>
Conclusions
The authors concluded that giving patients and their nurses accurate estimates of volume overload helps PD patients to manage volume and control BP.

**Abbreviations**: ANOVA, analysis of variance; BCM, BCM – Body Composition Monitor; BP, blood pressure; n, number of patients; PD, peritoneal dialysis.

<table>
<thead>
<tr>
<th>Table 11 Summary of results from the Luo et al. (2011) study</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Randomised</strong></td>
</tr>
<tr>
<td>n=80</td>
</tr>
<tr>
<td><strong>Efficacy</strong></td>
</tr>
<tr>
<td><strong>Primary outcome: Over-hydration status (litres±SD)</strong></td>
</tr>
<tr>
<td>Baseline: 2.30±1.95</td>
</tr>
<tr>
<td>6 weeks: 2.12±1.65</td>
</tr>
<tr>
<td>12 weeks: 1.72±1.51</td>
</tr>
<tr>
<td><strong>Selected secondary outcomes</strong></td>
</tr>
<tr>
<td><strong>Extracellular water (litres±SD)</strong></td>
</tr>
<tr>
<td>6 weeks: 15.80±3.43</td>
</tr>
<tr>
<td>12 weeks: 15.49±3.45</td>
</tr>
<tr>
<td><strong>Intracellular water (litres±SD)</strong></td>
</tr>
<tr>
<td>6 weeks: 16.50±3.96</td>
</tr>
<tr>
<td>12 weeks: 16.60±4.16</td>
</tr>
<tr>
<td><strong>Systolic blood pressure (mmHg±SD)</strong></td>
</tr>
<tr>
<td>6 weeks: 134.87±21.18</td>
</tr>
<tr>
<td>12 weeks: 132.99±19.47</td>
</tr>
<tr>
<td><strong>Diastolic blood pressure (mmHg±SD)</strong></td>
</tr>
<tr>
<td>6 weeks: 78.51±12.28</td>
</tr>
<tr>
<td>12 weeks: 77.63±12.04</td>
</tr>
</tbody>
</table>

**Abbreviations**: BCM, BCM – Body Composition Monitor; n, number of patients; SD, standard deviation.

*a*Statistical significance from baseline reading (p<0.05).

*b*Statistical significance between groups (p<0.05).
About this briefing

Medtech innovation briefings summarise the published evidence and information available for individual medical technologies. The briefings provide information to aid local decision-making by clinicians, managers and procurement professionals.

Medtech innovation briefings aim to present information and critically review the strengths and weaknesses of the relevant evidence, but contain no recommendations and are not formal NICE guidance.

Development of this briefing

This briefing was developed for NICE by York and Newcastle External Assessment Centre. The Interim process & methods statement sets out the process NICE uses to select topics, and how the briefings are developed, quality-assured and approved for publication.

Project team

York and Newcastle External Assessment Centre
Medical Technologies Evaluation Programme, NICE

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The following specialist commentators provided comments on a draft of this briefing:

- Christine Jowsey, Ward Sister, Skipton Dialysis Unit
- Dr Elizabeth Lindley, Clinical Scientist in Renal Care, Leeds Teaching Hospitals
- Sheila Hull, Staff Nurse, Airedale General Hospital, Keighley
• Dr Stanley Fan, Consultant Nephrologist, Barts Health NHS Trust

Declarations of interest

• Dr Elizabeth Lindley received hospitality from the device manufacturer while conducting education sessions abroad. Other members of her research team have previously accepted a salary from the manufacturer.

• Dr Stanley Fan is an investigator on 3 studies sponsored by the manufacturer.

No other relevant interests were declared.

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