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ORIGINAL ARTICLE

Changes in quality of life, health status and other patient-reported outcomes following simultaneous pancreas and kidney transplantation (SPKT): a quantitative and qualitative analysis within a UK-wide programme

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ABSTRACT

We examined quality of life (QoL) and other patient-reported outcome measures (PROMs) in 95 simultaneous pancreas and kidney transplant (SPKT) recipients and 41 patients wait-listed for SPKT recruited to the UK Access to Transplantation and Transplant Outcome Measures (ATTOM) programme. Wait-listed patients transplanted within 12 months of recruitment ($n = 22$) were followed 12 months post-transplant and compared with those still wait-listed ($n = 19$) to examine pre- to post-transplant changes. Qualitative interviews with ten SPKT recipients 12 months post-transplant were analysed thematically. Cross-sectional analyses showed several better 12-month outcomes for SPKT recipients compared with those still wait-listed, a trend to better health utilities but no difference in diabetes-specific QoL or diabetes treatment satisfaction. Pre- to post-transplant, SPKT recipients showed improved treatment satisfaction, well-being, self-reported health, generic QoL and less negative impact on renal-specific QoL ($ps < 0.05$). Health utility values were better overall in transplant recipients and neither these nor diabetes-specific QoL changed significantly in either group. Pre-emptive transplant advantages seen in 12-month cross-sectional analyses disappeared when controlling for baseline values. Qualitative findings indicated diabetes complications, self-imposed blood glucose monitoring and dietary restrictions continued to impact QoL negatively post-transplant. Unrealistic expectations of SPKT caused some disappointment. Measuring condition-specific PROMs over time will help in demonstrating the benefits and limitations of SPKT.

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Key words

diabetes, kidney transplant, patient-reported outcome measures (PROMs), quality of life, renal, simultaneous pancreas, simultaneous pancreas and kidney transplantation, transplantation

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Introduction

Simultaneous pancreas–kidney transplantation (SPKT) is generally considered the optimum treatment for selected patients with insulin-dependent diabetes and stage G5 chronic kidney disease (CKD) [1–4]. Pancreas transplantation provides glycaemic control without the need for exogenous insulin, can reduce the likelihood of further damage from diabetic complications [3] and extends life compared with kidney transplantation alone [5,6]. As patient and graft survival rates improve, the focus is shifting towards how SPKT can improve other important nonclinical outcomes that can help determine the ‘value’ of SPKT in health care [7]. One of the first steps in addressing this question is to ask patients themselves how their quality of life (QoL) and other aspects of their lives are impacted by their treatment, using patient-reported outcome measures (PROMs). Although it has been suggested that QoL improves following transplantation [8], the measures most commonly used in SPKT research assess health status not QoL [9]. For example, generic health status measures such as the Short Form SF-36 [10] and the EQ-5D [11,12] have shown that SPKT recipients report comparable outcomes to kidney-alone transplant recipients [13–15]. A small number of studies have also compared SPKT recipients with those still awaiting transplant and reported that SPKT recipients have better scores on the SF-36 [14–16]. These studies, however, are cross-sectional and do not include genuine measures of QoL, so they cannot tell us how QoL may be impacted by SPKT. For example, Posegger et al [16] measured the SF-36 in SPKT recipients (less than one year, 1–3 years or > 3 years post-transplant), and in those who were wait-listed for SPKT. SPKT recipients reported better outcomes, but no pre-transplant data were provided, so any differences may have been present pretransplant and not caused by the transplant.

Health status is only moderately associated with generic QoL [17] and is predicted by different variables from those predicting QoL in people with type 2 diabetes [18]. Relying on health status measures in clinical decision-making for transplantation risks overlooking

other aspects of life important to patients’ QoL [19,20]. The present study examines various PROMs, including generic and condition-specific QoL along with health status, in UK patients wait-listed for SPKT, and in those who received SPKT. To provide a fuller and clearer picture of the outcomes of SPKT over time, analyses were also conducted with a subsample of patients who provided PROMs data pretransplant as well as post-transplant. This study also conducted qualitative interviews to examine the experience of SPKT post-transplant, and its impact on QoL.

Methods

Participants and procedure

This study was conducted as part of the UK Access to Transplantation and Transplant Outcome Measures (ATTOM) programme [21]. ATTOM aimed to examine access to renal transplantation [22,23] and learn how to optimize UK transplant outcomes. It consisted of five work streams (i) examining factors that influence access to transplantation; (ii) examining factors that affect survival on dialysis and after transplantation; (iii) examining differences in QoL and other PROMs in patients undergoing dialysis or transplantation; (iv) conducting health economics analysis of alternate approaches to organ allocation; and (v) using the survival, health status, QoL, treatment satisfaction and costs to determine an optimal organ allocation policy for the UK. Specific ATTOM methods are detailed elsewhere [21]. Following ethical approval (East of England REC 11/EE/0120), and obtaining informed consent, participants were recruited from all UK renal and transplant units. The present study was part of work stream 3 that investigated detailed PROMs in patients undergoing various treatments for CKD. Across all 72 renal units in the UK, every patient < 75 years of age starting RRT from November 2011 to March 2013 was invited to take part in ATTOM. Of those patients recruited to ATTOM, the first patient fluent in English recruited to each centre each month who was either wait-listed for SPKT or received SPKT was invited to take part in work stream 3.

To reflect the design of research previously conducted, the first component of the study included cross-sectional analyses that focused on participants recruited within three months of receiving their SPKT ($n = 117$) and patients wait-listed for SPKT ($n = 41$; see Fig. 1). Wait-listed patients were matched to contemporaneous SPKT recipients on the basis of age (within 5 years), time on waiting list (± 100 days) and whether they were receiving dialysis before transplantation. Participants completed measures of health status and well-being at recruitment. Generic QoL, renal- and diabetes-specific QoL, and renal and diabetes current treatment satisfaction measures were completed three months later via telephone or post. Twelve months later, both patient groups completed all questionnaires again, plus change versions of the treatment satisfaction questionnaires which compared satisfaction with current treatment (e.g. transplant) and previous treatment (e.g. dialysis). During the follow-up period, 22 of the 41 wait-listed patients received SPKT. For this group, the initial questionnaires were completed pretransplant when still wait-listed, whilst the second set of questionnaires was completed 12 months post-transplant (see Fig. 1). The second component therefore involved analyses conducted with those participants with pre- and post-transplant data.

A third component of the detailed PROMs study used semi-structured interviews (conducted by AG) to explore in depth the effects of SPKT on QoL in ten SPKT recipients. Participants were invited to take part in an interview if they had (i) received SPKT and (ii) completed the Renal-Dependent QoL (RDQoL) measure [24] 12 months post-transplant. Participants were selected so that they were representative of ATTOM SPKT recipients for age, sex and ethnicity, and included participants with a range of scores indicating high, low and average impact of their renal condition on their QoL, to ensure the sample reflected the range of QoL outcomes of the overall population. Participants were informed that the interview would explore their questionnaire responses related to their QoL and treatment satisfaction (see Appendix S1). Interviews were audio-recorded and transcribed (*Median length* = 56mins, range = 41-91).

Outcome measures

A summary of all outcome measures can be found in Table S1. Condition-specific QoL was measured using the Audit of Diabetes-Dependent Quality of Life (ADDQoL) Questionnaire [25,26], modified for SPKT recipients (see Appendix S2), and the Renal-Dependent Quality of Life (RDQoL) Questionnaire [24]. These DQoL measures share

the same template. First, a single item asks participants to rate their present QoL providing a generic QoL measure (excellent +3 to extremely bad -3). Subsequent items assess the impact of diabetes (ADDQoL) or the renal condition (RDQoL) on QoL. Patients rate the impact of the condition on various aspects of life (-3 maximum negative impact to +1 positive impact), and the importance of each aspect for their QoL (very important (3) to not at all important (0)). Multiplying impact by importance ratings gives a weighted impact (WI) score for each item. Some of the items include preliminary questions to determine applicability to the individual (e.g. employment). WI scores are summed and divided by the number of applicable items to give an average-weighted impact (AWI) score (maximum negative impact -9 to most positive impact +3).

Well-being was measured by the Well-Being Questionnaire (W-BQ12) [27,28]. Higher scores indicate better well-being (range = 0-36). Health status was measured by the EQ-5D-5L [13,14], which involves rating five dimensions of health on five levels. These data were then converted into a population preference score called a health utility value, using the new value set for England [29,30] and methods encouraged by the National Institute for health and Clinical Excellence (NICE; <https://www.nice.org.uk/>). Higher health utility values indicate better health status, whilst lower scores indicate worse health status. They are measured on an interval scale with zero reflecting states of health equivalent to death and one reflecting perfect health. The EQ-5D also asks participants to rate 'your own health state today' on a visual analogue scale (EQ-VAS) from 100 (best health you can imagine) to 0 (worst health you can imagine).

The Diabetes Treatment Satisfaction Questionnaire status version (DTSQs) [31,32] assesses satisfaction with diabetes treatment. Six items are summed to give a treatment satisfaction score; higher scores indicate greater satisfaction (range = 0-36). The change version (DTSQc) [33,34] was developed to counteract ceiling effects commonly found in satisfaction measurement [33,34] and asks participants to compare their current treatment with their previous treatment (range: +18 much more satisfied now, to -18 much less satisfied now). Renal Treatment Satisfaction Questionnaire status and change versions (RTSQs and RTSQc) [35], modelled on the DTSQs and DTSQc, were also completed.

Analyses

Chi-squared tests and *t* tests were conducted to determine which, if any, demographic or medical factors

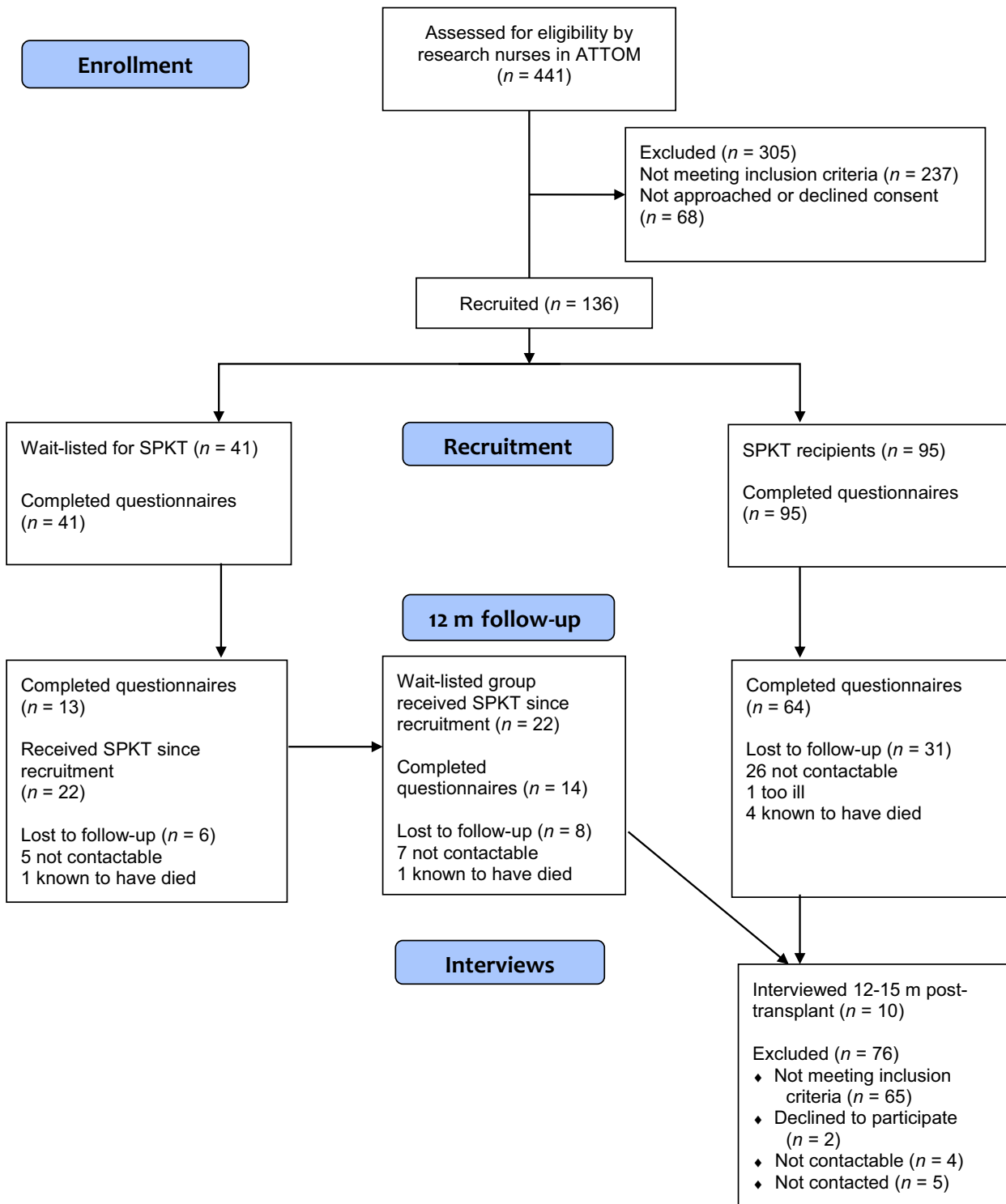


Figure 1 CONSORT diagram showing number of participants and timing of questionnaire completion

needed controlling for in subsequent analyses. Cross-sectional differences in outcomes in all participants who received SPKT ($n = 95$) and those still remaining wait-listed for SPKT ($n = 19$) at 12 months post-transplant/postrecruitment were conducted using one-way analyses

of covariance (ANCOVA) controlling for sex, education and previous treatment (dialysis versus predialysis). Analyses examining pre- and post-transplant differences over time were conducted using a series of 2 (group) x 2 (time) ANCOVAs with planned comparisons

(controlling for sex and pretransplant treatment). These analyses were undertaken with the 41 patients recruited when wait-listed, and who were either still wait-listed ($n = 19$) after 12 months, or subsequently transplanted ($n = 22$). One-way ANCOVAs controlling for sex, pre-transplant treatment and initial treatment satisfaction status scores were also conducted with these 41 patients, to examine differences between groups in treatment satisfaction change measures comparing satisfaction with treatment at 12 months post-transplant compared with previous renal or diabetes treatment (dialysis or insulin treatment regimen).

Thematic analyses of qualitative data, based on a pragmatic approach, were conducted according to established guidelines [36]. Initial coding (AG) established themes derived from the data. These enabled development of a coding framework (AG, MC, CB), which showed significant inter-rater agreement during subsequent coding (AG and JB). The coding, completed in MS Word, was entered into NVivo10 software (QSR International, USA) for qualitative analysis.

Results

The demographics of the 117 patients who underwent SPKT during ATTOM and the 19 patients remaining wait-listed at 12 months are shown in Table 1. Twenty-five SPKT recipients (21%) were transplanted before starting dialysis (Table 1), whilst five (26%) wait-listed patients were not on dialysis when first listed. At 12 months, 26 (19.1%) participants did not return completed measures, 14 (10.3%) could not be contacted, 1 (0.1%) person was too ill, and 4 people (2.9%) were known to have died. There were no significant differences between responders and nonresponders in sex, ethnicity, employment status, civil status, education, renal replacement therapy (RRT), type of donor (donation after brainstem death (DBD) or donation after circulatory death (DCD)), recruitment PROMs or utility measures.

Differences in outcomes

A significantly higher proportion of women were wait-listed for SPKT (68.4%) than received SPKT (42.7%) compared with men (31.6% wait-listed patients were men, 57.3% received SPKT; $\chi^2 = 4.3$, $df = 1$, $P = 0.04$). Those remaining wait-listed at 12 months were more likely to have the minimum standard schooling than those receiving a transplant ($\chi^2 = 4.6$, $df = 1$, $P = 0.03$). There was no difference in education level in those

patients who were wait-listed at recruitment and who either went on to have a transplant, or remained wait-listed ($\chi^2 = 6.34$, $df = 3$, $P = 0.09$).

Among recipients of SPKT, outcomes at 12 months did not differ by donor type (DBD or DCD; $ps > 0.05$), or previous RRT ($ps > 0.05$). However, those who received dialysis prior to transplantation reported greater improvements over time in generic QoL ($M = -0.3$, $SD = 1.5$ to $M = 1.5$, $SD = 0.8$; $P = 0.01$), renal treatment satisfaction ($M = 51.8$, $SD = 11.9$ to $M = 72.8$, $SD = 5.4$; $P < 0.001$) and diabetes treatment satisfaction ($M = 26.9$, $SD = 8.1$ to $M = 34.1$, $SD = 4.1$; $P = 0.02$) than those pre-emptively transplanted. Subsequent analyses controlled for sex and previous RRT, whilst level of education was also controlled for in cross-sectional analyses.

Cross-sectional analyses compared all patients who received a transplant to those still wait-listed at 12 months, controlling for differences in sex, previous RRT and education (Table 2). SPKT recipients reported better generic QoL ($P = 0.01$), total well-being ($P < 0.001$), health status (EQ-VAS, $ps < 0.001$), renal treatment satisfaction ($P = 0.03$) and less negative impact of the renal condition on QoL compared with those wait-listed ($P = 0.01$). There were no between-group differences in impact of diabetes on QoL ($P = 0.9$) or diabetes treatment satisfaction ($P = 0.8$), or health utility values ($P = 0.09$) at 12 months. These analyses do not consider pretransplant data and therefore do not take account of baseline differences or changes over time.

For the subsample of 41 patients recruited whilst wait-listed, we examined differences between those who were still wait-listed at one year ($n = 19$) and those who subsequently had a transplant ($n = 22$), controlling for sex and previous RRT. There were no significant differences between groups at recruitment, although there was a trend for those patients who went on to receive SPKT to have better health utility values ($P = 0.08$). As can be seen in Figs 2 and 3, significant interaction effects between groups and over time were found for generic QoL, renal-specific QoL (RDQoL AWI scores), well-being, EQ-VAS self-reported health and renal treatment satisfaction ($ps < 0.05$). For these outcomes, those patients who remained wait-listed reported no change in scores over time. In contrast, those who received SPKT reported improved generic QoL ($P = 0.01$), well-being ($P = 0.05$), EQ-VAS self-reported health ($P = 0.01$), renal treatment satisfaction (RTSQs; $P < 0.001$) and less negative impact of their renal condition on QoL (RDQoL AWI scores; $P = 0.04$). These

Table 1. Summary of demographic characteristics

	Transplant (<i>n</i> = 117)	Wait-listed (<i>n</i> = 19)	Difference between groups
Variable	Mean (SD)	Mean (SD)	<i>P</i>
Age (years)	42.3 (8.4)	42.3 (6.8)	0.99
Variable	<i>n</i> (%)	<i>n</i> (%)	<i>P</i>
Sex: Female	50 (42.7)	13 (68.4)	0.04
Previous experience of SPKT failure	10 (8.5)	2 (10.5)	0.83
<i>Primary renal diagnosis</i>			0.88
Diabetes (type 1)	108 (92.6)	18 (94.7)	
Diabetes (type 2)	1 (0.8)	1 (5.3)	
Renal vascular disease (hypertension)	1 (0.8)	0 (0.0)	
Glomerulonephritis	1 (0.8)	0 (0.0)	
IgA nephropathy	1 (0.8)	0 (0.0)	
Unspecified diagnosis	1 (0.8)	0 (0.0)	
Missing	4 (3.4)	0 (0.0)	
<i>Pretransplant treatment</i>			0.75
Predialysis	25 (21.4)	5 (26.3)	
Peritoneal dialysis (PD)	34 (29.1)	3 (15.8)	
Haemodialysis (HD)	50 (42.7)	11 (57.9)	
Failing transplant	2 (1.7)	0 (0.0)	
Missing	6 (5.1)	0 (0.0)	
<i>Comorbid conditions</i>			
Heart disease	10 (8.8)	2 (10.5)	0.81
Heart failure	1 (0.9)	1 (5.3)	0.15
Cardiovascular disease	10 (8.8)	4 (21.1)	0.25
Pulmonary disease	13 (11.5)	2 (10.5)	0.90
Respiratory disease	5 (4.4)	0 (0.0)	0.35
Malignancy	2 (1.8)	0 (0.0)	0.56
Mental illness	15 (13.3)	2 (10.5)	0.74
<i>Marital status</i>			0.77
Single	38 (32.5)	5 (26.3)	
Living with partner	10 (8.5)	3 (15.8)	
Married	47 (40.2)	8 (42.1)	
Divorced/Separated	12 (10.2)	2 (10.5)	
Widowed	3 (2.6)	0 (0.0)	
Missing	7 (6.0)	1 (5.3)	
<i>Ethnicity</i>			0.49
White	97 (82.9)	15 (78.9)	
Black	6 (5.1)	2 (10.5)	
Asian	4 (3.5)	0 (0.0)	
Mixed	2 (1.7)	1 (5.3)	
Missing	8 (6.8)	1 (5.3)	
<i>Education</i>			0.15
Minimum standard schooling	13 (11.1)	5 (26.3)	0.033
Completed secondary education with qualifications	36 (30.8)	4 (21.1)	0.592
Higher education	14 (11.9)	4 (21.1)	0.597
Other qualifications (e.g. NVQ1-5)	48 (41.1)	5 (26.3)	0.431
Missing	6 (5.1)	1 (5.2)	

Higher education qualifications include bachelor's degree, higher degree. Secondary education qualifications include A-level and/or GCSE.

outcomes were significantly better for SPKT recipients at 12 months. Diabetes-specific QoL (ADDQoL AWI scores) remained stable over time for both groups ($P = 0.2$). At 12 months, SPKT recipients had significantly better health utility values than those still wait-

listed ($P = 0.01$), but neither group showed significant changes in values over time ($P = 0.6$). However, 20.5% of SPKT recipients had worse health utility scores post-transplant, but many fewer reported worse QoL scores post-transplant (6.3% reporting worse generic QoL and

Table 2. Summary of means (*M*) and standard errors (SE) of outcomes (controlling for sex, education and pretransplant treatment) across groups at 12 months post-transplant/postrecruitment

a. Group at 12 months Patient outcomes	Transplant (<i>n</i> = 78)		Wait-listed (<i>n</i> = 12)		<i>F</i>	<i>df</i>	<i>P</i>
	<i>M</i>	SE	<i>M</i>	SE			
Generic QoL (RDQoL)	1.23	0.14	0.04	0.37	8.85	83	0.004
Renal-specific QoL (RDQoL AWI)	-2.62	0.21	-4.43	0.59	7.95	81	0.006
Total well-being (W-BQ12)	24.59	0.84	15.92	2.34	11.82	81	<0.001
Health status (EQ-VAS ratings)	76.22	2.20	45.92	5.74	23.85	82	<0.001
Health utility values (EQ-5D-5L)	0.78	0.02	0.64	0.07	3.04	81	0.085
Current renal treatment satisfaction (RTSQs)	69.82	0.97	63.63	2.54	5.11	82	0.027
Change in renal treatment satisfaction (RTSQc)	31.29	1.16	12.77	3.17	29.69	81	<0.001
Diabetes-specific QoL (ADDQoL AWI)	-3.58	0.25	-3.51	0.64	0.01	80	0.923
Current diabetes treatment satisfaction (DTSQs)	32.66	0.74	32.26	1.90	0.04	79	0.849
Change in diabetes treatment satisfaction (DTSQc)	14.35	0.84	4.40	2.45	14.59	74	<0.001

QoL = quality of life; RDQoL = Renal-Dependent Quality of Life Questionnaire; AWI = average-weighted impact score; EQ-VAS = visual analogue scale; RTSQs = Renal Treatment Satisfaction Questionnaire – status version; RTSQc = Renal Treatment Satisfaction Questionnaire – change version; ADDQoL = Audit of Diabetes-Dependent Quality of Life Questionnaire; DTSQs = Diabetes Treatment Satisfaction Questionnaire – status version; DTSQc = Diabetes Treatment Satisfaction Questionnaire – change version.

4.9% more negative impact on their renal-specific QoL). Diabetes treatment satisfaction (DTSQs) increased over time ($P < 0.01$), with no between-group differences ($P = 0.9$; Fig. 2).

Controlling for sex, previous RRT and pretransplant RTSQs scores, there was greater improvement in satisfaction with renal treatment at 12 months compared with baseline treatment (RTSQc) for those who were recruited whilst on the waiting list who subsequently received an SPKT ($M = 31.6$, $SE = 3.9$) than for those who remained wait-listed ($M = 11.9$, $SE = 4.8$; $F_{(1, 17)} = 9.6$, $P = 0.007$; see Fig. 3). The DTSQc also showed greater improvements in satisfaction with diabetes treatment in SPKT recipients ($M = 13.9$, $SE = 2.1$) compared with those wait-listed ($M = 5.8$, $SE = 2.9$; $F_{(1, 12)} = 5.1$, $P = 0.04$). This is in contrast to the DTSQs, where 75.7% recipients scored at or near ceiling prior to transplantation, and 83.6% at 12 months post-transplant, showing that the majority of participants could not improve their status scores.

Qualitative interviews

Participants discussed the impact of their renal condition and diabetes on their QoL, the ways in which their transplant had minimized the negative impact of their conditions on their QoL, and how their diabetes

continued to impact negatively on their QoL post-transplant. Illustrative examples of these themes can be seen in Table 3. Before transplantation, recipients reported that work, leisure activities, physical ability, diet and relationships were all negatively impacted by their renal condition. Diabetes led to eyesight problems, neuropathy, mobility problems and undesirable dietary restrictions, and had a negative impact on social activities and work. Post-transplant, participants reported improved physical ability, greater independence and dietary freedom. Despite having a functioning pancreas transplant, recipients still reported that their diabetes negatively impacted their QoL. Complications such as retinopathy were still affecting the ability to work and drive. Having expectations of transplant that were not realized (e.g. size of scar) led to distress and negatively impacted QoL post-transplant. For example, one woman was shocked by the size of her scar post-transplant, which led to feelings of anxiety about being considered 'damaged goods'. This made her feel less able to disclose her condition to others, which she perceived as an obstacle in finding a partner. Many participants were anxious about how long their transplant would remain functional. Six of the ten SPKT recipients interviewed more than one year post-transplant reported still restricting their diet and/or checking their blood sugars frequently, as a result of this anxiety.

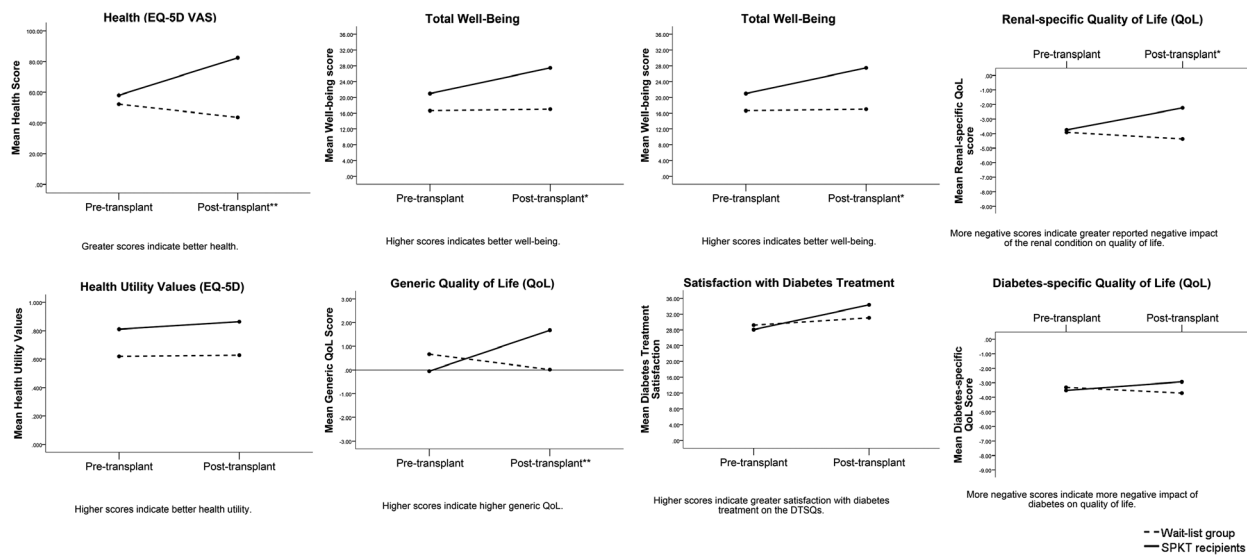


Figure 2 Differences in outcomes (controlling for sex and previous renal replacement therapy) at pretransplant/recruitment and at 12m post-transplant/12m postrecruitment in those who remained wait-listed for an SPKT ($n = 19$), and those who received an SPK transplant after recruitment ($n = 22$). Note: *indicates main effects of differences between groups post-transplant: $*P < 0.05$; $**P < 0.01$; $***P < 0.001$. EQ-5D VAS = visual analogue scale rating; RDQoL = Renal-Dependent Quality of Life Questionnaire; AWI score = average-weighted impact score; ADDQoL = Audit of Diabetes-Dependent Quality of Life Questionnaire. RTSQs = Renal Treatment Satisfaction Questionnaire (status version); DTSQs = Diabetes Treatment Satisfaction Questionnaire (status version)

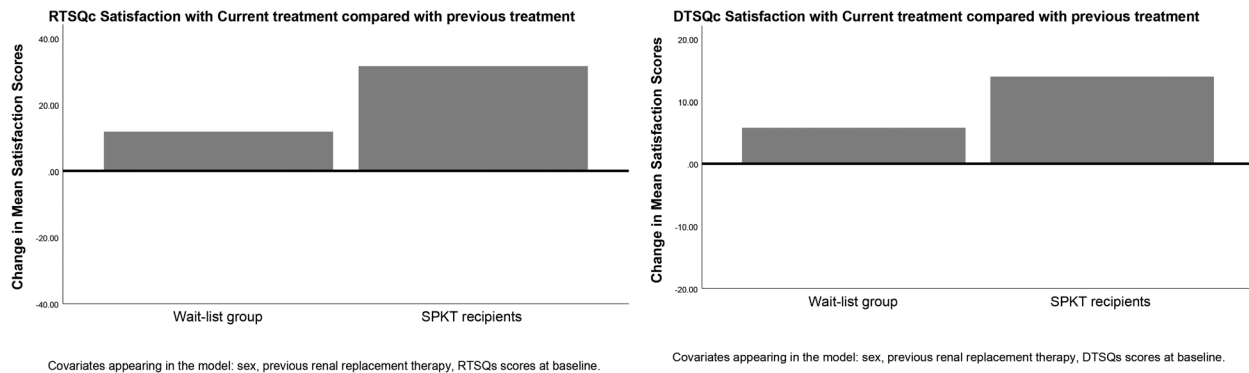


Figure 3 Bar graphs showing differences in treatment satisfaction change scores (controlling for sex, previous renal replacement therapy and baseline treatment satisfaction scores) in those who remained wait-listed for an SPKT ($n = 19$), and those who received an SPKT after recruitment ($n = 22$). Note: RTSQc: Renal Treatment Satisfaction Questionnaire (change version); DTSQc Diabetes Treatment Satisfaction Questionnaire (change version). Positive scores indicate improved satisfaction with the current treatment compared with the previous treatment. Negative scores indicate a deterioration in satisfaction with the current treatment compared with the previous treatment. A score of zero indicates no change in satisfaction. Main effects between groups for RTSQc and DTSQc are significant ($ps < 0.05$)

Discussion

This study shows some positive benefits of SPKT on patient-reported outcomes. The negative impact of participants' renal conditions on QoL reduced following transplantation, but surprisingly, the negative impact of diabetes on QoL showed no such improvement. This finding can be explained in part by the qualitative findings, which show that although participants reported

positive changes, their QoL continued to be impaired by long-standing diabetes-related complications. These complications limited the positive impact of the transplant on their QoL. Previous research has shown that although SPKT recipients reported better physical health outcomes [1-6], they did not report better mental health when compared with kidney-only recipients [14]. Although not actively encouraged to continue to check their blood

glucose levels by medical staff, many participants reported anxiety surrounding graft loss. Anxiety led many to adopt self-imposed dietary restrictions. Frequent blood glucose testing was also commonly carried out more than one year post-transplant. Participants believed these measures supported their graft survival. This anxiety and uncertainty about the future has been shown in previous research [37]. For example, Kwiatkowski *et al.* [38] reported that in 19 SPKT recipients, all reported greater life satisfaction, but after an average of four years post-transplant, only four had returned to work, 12 reported fear of graft loss, 14 checked their glucose levels daily, and 8 reported feeling sad or depressed. Dietary freedom is the aspect of life that is usually most damaged by diabetes, and is considered by patients to be very important for QoL [25,26,39], so continuing to restrict dietary freedom, when not deemed medically necessary, may continue to damage QoL post-transplant. SPKT recipients may require guidance and support about how to protect and monitor their SPKT and maintain a healthy diet, whilst also protecting their QoL. To improve diabetes-specific QoL, SPKT recipients could be encouraged to challenge their behaviour and beliefs by checking and recording one fasting and one postprandial blood glucose per day for two weeks of continued restricted diet followed by two weeks of dietary freedom and discussing the results with their doctor, diabetes specialist nurse or health psychologist. Such a behavioural change intervention has the potential to improve QoL but needs pilot testing with monitoring of anxiety as well as QoL. More generally, although some patients felt well-prepared for the realities of the experience of SPKT and its effects on their lives, others did not. The greater the disparity between expectations and reality (e.g. the size of post-transplant scar), the more distress experienced by participants. More precise information, prior to listing for SPKT, is needed, to ensure that the decision to be wait listed for SPKT is fully informed and avoid the shock and regret that may otherwise follow overly optimistic expectations.

Satisfaction with diabetes treatment, measured by the DTSQ status measure, did not improve following transplantation, but most participants reported very high/maximum levels of satisfaction pretransplant. These ceiling effects were overcome by the DTSQ change version, which allowed participants to report greater satisfaction at follow-up even when very satisfied at baseline. The DTSQc showed significantly greater improvements in satisfaction in those transplanted compared with those still wait-listed. This highlights the importance of using both status and change versions of treatment satisfaction questionnaires in such research.

SPKT recipients reported greater well-being and generic QoL at 12 months compared with those wait-listed and showed improvements in scores pre- to post-transplantation. Transplant recipients reported better self-rated health status pre- to post-transplant in the form of EQ-VAS ratings. Transplant recipients tended to have better health utility values pretransplant than those who remained wait-listed, and this trend became significant at 12 months, primarily because of baseline differences as there were no significant changes over time. Although SPKT can help improve long-term survival and prevent worsening of diabetes complications, it is not an immediately life-saving operation, so it is particularly important to have a complete picture of patient-reported outcomes when assessing cost-effectiveness including all pros and cons. Focusing only on the health utility measure would lead to the benefits of SPKT being underestimated, as they do not reflect the improvements seen with other PROMs. Going forward, it will be valuable to monitor patient-reported outcomes routinely in all wait-listed patients, to determine changes over time and with a longer follow-up post-transplantation, and such studies are underway.

Those on dialysis prior to transplantation reported greater improvements in generic QoL and satisfaction with both diabetes and renal treatments when compared with those pre-emptively transplanted, although no differences were apparent in 12-month cross-sectional analyses. The pre-emptive group made fewer gains over time, whilst those who were receiving dialysis reported greater improvements until they were comparable to those pre-emptively transplanted. Pre-emptive transplantation is considered by many to be more beneficial for patients, but these findings suggest once pretransplant scores are controlled, there are no group differences 12 months post-transplant.

This is the first study to measure renal-specific and diabetes-specific QoL in SPKT and is the first to examine quantitative changes in PROMs pre- to post-transplant, together with qualitative data to understand the PROMs findings. However, this study had some limitations. The sample for whom pretransplant data were available was relatively small, with attrition over time. Despite this, most previous research has been cross-sectional, so although the small sample size may limit the generalizability of our longitudinal sample, the overlapping much larger cross-sectional sample replicates some of the findings (e.g. in QoL and well-being) but not others where it can be seen that pretransplant measures are important for understanding 12-month outcomes (e.g. ceiling effects at baseline in treatment satisfaction:

Table 3. Summary of qualitative themes with illustrative quotations

Theme	Illustrative quotations
Impact of renal condition before transplant	<p>Physical ability:</p> <ul style="list-style-type: none"> • I hadn't realised how tired I was getting. Woman, pre-emptive SPKT. • I was constantly very tired; looked very yellow, gaunt, and just really running out of energy. And I kept getting gout and cellulitis. Man, pre-emptive SPKT. <p>Leisure activities:</p> <ul style="list-style-type: none"> • I had stopped going out. . . at night time I still had to plug into the machine and everybody said are you coming out and I'd be like no I have to plug in by 10 o'clock. Woman, SPKT following CAPD. • I had to make an effort of not going anywhere very far. I couldn't go abroad because I had to be at a maximum four hours away from the hospital in case (the call for a transplant) came through. Man, pre-emptive SPKT. <p>Work:</p> <p>I sort of gave up work as well cos I just you know I couldn't cope. . .I gave up work because I knew that my health was deteriorating and I thought it was best for myself and my employer that I gave up work to look after my health. Woman, SPKT following HD.</p> <p>Diet:</p> <ul style="list-style-type: none"> • When I was on dialysis (before the transplant), I was on a low potassium diet which was very, very strict and I could only drink 500mls a day. Man, SPKT following HD. <p>Relationships:</p> <ul style="list-style-type: none"> • I mean obviously I was at home all the time but I wasn't physically able to do a great deal so it still meant that I was putting a lot of pressure on my partner. She was going to work and then she was coming home and cooking and things like that. Man, SPKT following CAPD.
Impact of diabetes before transplant	<p>Neuropathy or mobility:</p> <ul style="list-style-type: none"> • I had trouble with my eyes, then my nerve damage. Man, pre-emptive SPKT. • As a by-product, or maybe partly a by-product, I got what's called Charcot foot. Man, pre-emptive SPKT. • I'm limited to the use of that hand. Woman, SPKT following HD. <p>Eyesight:</p> <ul style="list-style-type: none"> • Looking at a computer screen, unless I've got the magnifier up, I can't see normal print. I think for instance like if I wanted to like sew something, I couldn't thread a needle and that would be because of my eyesight (from the diabetes). Woman, SPKT following HD. <p>Lifestyle:</p> <ul style="list-style-type: none"> • The main thing, the other thing is about the diabetes, that was SO restrictive, it was just ah well I never actually, I mean I knew it was bad, it was a full-time thing. You couldn't get rid of it, and you had to; I had to watch you know it was all through the night I was doing blood tests probably um every hour usually during the night. Through the day wasn't that bad but you had to just watch; your blood sugars were all over the place you know they'd be high and then you just couldn't guess, well you couldn't work out what was happening. That was the main thing. Man, SPKT following HD. <p>Work:</p> <ul style="list-style-type: none"> • I was getting fed up of being a diabetic because I was missing out on a lot of things in work. And also, I was losing my job because of being a diabetic. I used to be a driver driving a seven-and-a-half-ton truck but I lost my job because the government brought in a rule that you can't drive an HGV when you're diabetic so I lost my job. Man, pre-emptive SPKT. <p>Social activities/self-confidence:</p> <ul style="list-style-type: none"> • I think the diabetes initially it used to put a strain on social activities again to be honest with you. I constantly needed the loo. . .It was things like travelling were a bit of an issue, with driving. Man, SPKT following CAPD.
Minimizing impact post-transplant	<ul style="list-style-type: none"> • I mean it has cured the diabetes. Man, SPKT following HD. • I'm grateful for both organs. It's prolonged my life, it's stopped me from going to hospital 3 times a week for dialysis, it's given me lots of energy, I've got back my, you know some of my independence. Woman, SPKT following HD. • Well as far as I'm concerned, I'm just, my life is as I would be as I was before I had to have dialysis. Man, SPKT following HD. • I'm not on insulin anymore; I'm not insulin dependent anymore. And I can eat within reason. . . everything that is put in front of me, and that's including chocolate! Man, pre-emptive SPKT. • It's much better; I'm much freer with what I can eat. Man, pre-emptive SPKT.

Table 3. Continued.

Theme	Illustrative quotations
Ongoing negative impact of diabetes post-transplant	<p>Ongoing complications:</p> <ul style="list-style-type: none"> • It's the damage done beforehand, it's not repairable, and it's not going to get any better. Woman, SPKT following HD. • I think the health situation is much better, ... It's just the legacy of personal, financial, career things around it that have possibly not turned out as well...it's not over. I just feel that with other conditions you get fixed and then it is fixed. That's the difference. Woman, SPKT following CAPD. • I just sometimes I still feel like I have no future... for example if I'm going to get a partner now, I don't know if some people from certain cultures will be like 'oh no don't touch her because her life expectancy or health isn't too good, how's she gonna have kids?' I still feel... that kind of feeling of damaged goods. Woman, SPKT following CAPD. • The (driving) licence has got to be renewed every three years; I'm on a three-yearly licence. It's due for renewal this year so this is where the question (of whether I still have diabetes is going to come up. Man, pre-emptive SPKT. • If you're diabetic if you apply for jobs, I know because under the Disability Act they're supposed to ignore it. But they don't and I've had this time and time again from other people who I know who are diabetic, who know damn well it's not ignored. And in that respect, I think it affected my career and what I could do in the past. A lot of people are very nervous about taking someone on with diabetes and um, I think they still would be you know even with having the pancreas transplant. I think they still would be. Man, pre-emptive SPKT. • Even though I'm not insulin dependent anymore I'm still classed as a diabetic. Man, pre-emptive SPKT. • In my head I was always thinking... when that call comes through that they've got your kidney, everything will be fixed and everything will go back to normal. I'll get my health back, I'll be able to do activities, I'll be able to go out, I wouldn't have a tube in my stomach. But then the same anxieties from the tube in my stomach and from people seeing the tube has now been transferred to people seeing my scar, which is quite a large scar. Woman, SPKT following CAPD. • Just because I now no longer have to take insulin and I am at the moment no longer a diabetic, doesn't mean that I won't still... there is still a possibility that any of these complications could still happen to me, any time you know even late in life because I was diabetic for 30 years. Man, SPKT following HD. <p>Continued impact on diet:</p> <ul style="list-style-type: none"> • If I get a cold drink from a shop or something like that, I will still automatically go for the diet option. Man, SPKT following CAPD. • I couldn't bring myself to eat anything (sweet) after so long. Man, pre-emptive SPKT. • I'd been on a carbohydrate counting diet since I was 8 and rather weirdly, I'm still on the same thing, from choice. It's not that I stand there religiously with a pair of scales, but all the time I'm eating I'm still very, very aware that potato is about 40 grams. I just can't get it out of my system. Man, pre-emptive SPKT. <p>Blood glucose monitoring:</p> <ul style="list-style-type: none"> • (I check my blood glucose) daily at the moment. Well once a day, maybe once a day. Once a day just after I've had my breakfast and just before I go out that's when I check it and I don't bother checking it any other time. I still do, just, just to be safe and to be sensible about it and just put my mind at rest. Man, SPKT following HD. • I've still got to be careful with what I'm eating, I've got to watch what I eat. I monitor myself every few days... I do it every two days and I do it twice every two days. Man, pre-emptive SPKT. • I test my blood once in a blue moon, once a week now just every now and again. That's for my own benefit rather than anything else. The hospital told me I don't need to but they do

health utility values that were better at baseline in those who went on to receive SPKT versus those remaining on the waiting list). With the longitudinal data, we can also see that PROMs were better at baseline in those

who were pre-emptively transplanted compared with those transplanted following a period on dialysis and it was the latter who showed most benefit from SPKT. There was a higher proportion of women than men still

Table 3. Continued.

Theme	Illustrative quotations
Expectations of transplant	<p>ask me every time I go if I have done and what it was! I keep doing it I think more for their sake than mine now but I do it every now and again. Man, SPKT following HD.</p> <ul style="list-style-type: none"> • In my head I was always thinking...everything will be fixed and everything will go back to normal, but it did shock me because I didn't think (the transplant scar) would be from breast bone down to the groin. I never thought it would be that big... when I saw the huge staples, I just felt they didn't care enough to even use some neat stitches, they used staples. Woman, SPKT following CAPD. • When (healthcare staff) are giving out all the information before you have the transplant, the last thing that they want to do is to put you off by saying well you know, you could be really ill afterwards... but I don't actually think that you ever really prepare yourself for that because you hope of course that that's not going to be you, and you don't expect it to be you either, even though you know that it could be, you don't think it will be. Woman, pre-emptive SPKT. • (The professor) who's the main transplant man, he said ... once you've had (the transplant) done, you'll feel so appalling, you'll think why on earth have I done that? So, they are, actually they're brutally honest and actually I think they prepare you extremely well. Man, pre-emptive SPKT.

wait-listed one year postrecruitment compared with those transplanted. UK-wide figures for 2011-2014 showed similar rates for men and women on the nationwide waiting list (52% men), and those transplanted (55% men) [40-42], despite the fact that the UK kidney offering policies do not discriminate on sex or educational background. It is not clear why we found a bias in SPKT favouring men during the period of our study (2011-2014). The analysis controlled for these factors when analysing the PROMs data to minimize the effects of any bias. Those who took part at 12 months post-transplant all had functioning grafts, so the findings do not reflect the QoL and PROMs of those few patients whose transplants failed. Patients who experience failed transplants are likely to have more negative outcomes in terms of PROMs and would need to be considered in evaluating the overall impact of SPKT. The comparative wait-listed group was small, but there were no baseline differences between 12-month responders and nonresponders, suggesting that our responders were sufficiently representative of the original larger sample. Twelve-month follow-up may be insufficient for the full benefits of SPKT to emerge and current work includes a longer-term follow-up of these ATTOM patients. As this study focused on patient-reported outcomes, we do not have detailed clinical outcome data such as the number of post-transplant complications experienced by patients, but any effects of such complications on QoL and treatment satisfaction will have been captured by the PROMs used.

Measuring PROMs pretransplant increased our understanding of changes over time suggesting transplantation improved well-being, QoL, treatment satisfaction and patient-reported health (but not health utility values).

Measuring condition-specific PROMs over time demonstrates the benefits and limitations of SPKT and identifies opportunities for further QoL improvements through, for example, guidance and support about how best to protect and monitor their SPKT, whilst avoiding the quality of life damaging and medically unnecessary dietary restrictions and blood glucose monitoring.

Authorship

AG contributed to the analysis plan, development of the qualitative interview schedule, development of the coding framework, conducted the interviews, coded and analysed the data, drafted the manuscript, and edited and approved the final submission. MC contributed to the design of the qualitative study, development of the interview schedule, development of the coding framework, provided feedback on initial drafts of the manuscript, and edited and approved the final submission. JB contributed to decisions about study procedures, conducted quantitative data collection and telephone interviews, coded the data, provided feedback on initial drafts of the manuscript, and edited and approved the final submission. HD contributed to the design of the qualitative study, development of the interview schedule, and edited and approved the final submission. RJ, GCO, RR, CRVT, WM, JF and CD contributed to the design, organization and conduct of the wider ATTOM programme including data collection for this sub-study, and provided feedback on the interview schedule, and edited and approved the final submission. JAB, RR, GCO, CJEW, CRVT, CD and JF conceived the ATTOM programme, contributed to the design of the study, provided feedback on the interview schedule, and edited and approved the final

submission. CB contributed to the design of the studies, development of the interview schedule, development of the coding framework, analysis plans, edited early drafts of the manuscript, and edited and approved the final submission. AG and CB act as guarantor and accept full responsibility for the work and/or the conduct of the study, had access to the data and controlled the decision to publish. The corresponding author attests that all listed authors meet authorship criteria and that no others meeting the criteria have been omitted.

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Conflict of interest

Prof Watson reports personal fees from GlaxoSmithKline outside the submitted work. Prof. Clare Bradley is a director and majority shareholder of a company, Health Psychology Research (HPR) Ltd, which licenses her patient-reported outcome measures, for others to use

and manages their linguistic validation into other languages. HPR Ltd paid 50% of CB's salary plus overheads to her college throughout the five years of ATTOM funding. Questionnaires managed by HPR Ltd include the RDQoL, RTSQ, ADDQoL, DTSQ and W-BQ12 used in the ATTOM programme. CB owns the copyright in all of these instruments and, when they are licensed for use by commercial companies, receives royalties. All other authors declared no competing interests. The results presented in this paper have not been published previously in whole or part, except in abstract format.

SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of the article.

Access to Questionnaires: Please visit www.healthpsychologyresearch.com for all questionnaires except the EQ-5D-5L which is available from www.euroqol.org.

Appendix S1 Interview schedule for semi-structured interviews with SPKT recipients.

Appendix S2 Psychometric properties of the ADDQoL for SPKT and DTSQs/c for SPKT recipients.

Table S1 Summary of outcome measures.

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