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SPUR: psychometric properties of a patient-reported outcome measure of medication adherence in type 2 diabetes

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ABSTRACT

Introduction Poor medication adherence is associated with worsening patient health outcomes and increasing healthcare costs. A holistic tool to assess both medication adherence and drivers of adherence behaviour has yet to be developed. This study aimed to examine SPUR, a multifactorial patient-reported outcome measure of medication adherence in patients living with type 2 diabetes, with a view to develop a suitable model for psychometric analysis.
Furthermore, the study aimed to explore the relationship between the SPUR model and socio-clinical factors of medication adherence.

Research design and methods The study recruited 378 adult patients living with type 2 diabetes from a mix of community and secondary-care settings to participate in this non-interventional cross-sectional study. The original SPUR-45 tool was completed by participants with other patient-reported outcome measures for comparison, in addition to the collection of two objective adherence measures; HbA_{1c} and the medication possession ratio (MPR).

Results Factor and reliability analysis conducted on SPUR-45 produced a revised and more concise version (27-items) of the tool, SPUR-27, which was psychometrically assessed. SPUR-27 observed strong internal consistency with significant correlations to the other psychometric measures (Beliefs about Medication Questionnaire, Diabetes Treatment Satisfaction Questionnaire, Medicine Adherence Rating Scale) completed by participants. Higher SPUR-27 scores were associated with lower HbA_{1c} values and a higher MPR, as well as other predicted socio-clinical factors such as higher income, increased age and lower body mass index.

Conclusions SPUR-27 demonstrated strong psychometric properties. Further work should look to examine the test–retest reliability of the model as well as examine transferability to other chronic conditions and broader population samples. Overall, the initial findings suggest that SPUR-27 is a reliable model for the multifactorial assessment of medication adherence among patients living with type 2 diabetes.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ To our knowledge, this is the first UK study to assess the psychometric properties of a holistic patient reported outcome measure (PROM) that includes four key domains of medication adherence behaviour.
⇒ This cross-sectional study included a broad sample (n=378) of both hospital and community patients living with type 2 diabetes.
⇒ Validation was conducted using three additional PROMs as comparators in addition to a wide range of statistical methods including Monte Carlo parallel analysis, exploratory factor analysis and reliability testing.
⇒ The study was able to capture objective adherence data in the form of medication possession ratios and HbA_{1c} despite the challenges posed by COVID-19, providing additional evidence for validation.
⇒ COVID-19 prevented test–retest reliability analysis, hence further testing to confirm this validation component is required.

INTRODUCTION

The WHO estimate only 50%[1] of those living with a chronic condition are adherent to their medication, with the term 'medication adherence' (MA) being broadly defined as the extent to which a patient takes their medicines as prescribed.[2] A 2018 review[3] reports the cost of non-adherence across Europe and the USA with ranges from €1.25 billion to US$290 billion annually. Despite an arguably clear definition, however, the determinants of MA are often complex and multi-factorial.[4] Patients' confidence managing their medicines (self-efficacy), support from friends and family (interpersonal relationships), and clear communication from a prescriber (patient–physician relationship) are but a few examples of drivers that can play a role in MA.[4 5] One population of particular interest in respect to MA is people living with type 2 diabetes.

As of 2014, approximately 8.5%[6] of the global adult population were affected by diabetes, with the vast majority reporting a type 2 diabetes diagnosis. Ciechanowski *et al*[7] have reviewed the impact of psychosocial factors on adherence to both lifestyle

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measures and oral antiglycaemic treatment. Patients (n=367) were recruited with a spectrum of depression severity diagnoses. The number of patients considered to be non-adherent to their daily medication regimen was recognisably more prominent in those with high severity (15%, n=55) compared with those with low grade depression (7%, n=26). Furthermore, validated tools such as the Diabetes Knowledge Assessment have identified relationships between patients' lack of knowledge and poor adherence.[8] Unsurprisingly, numerous studies have implicated poor adherence in type 2 diabetes with higher hospital admission rates, increased length of stay as well as poorer admission outcomes.[9–11]

Several methods have been proposed to assess MA. The Morisky Medication Adherence Scale (MMAS-8),[12] an example of a patient reported outcome measure (PROM), examines patient behaviour as the primary determinant for assessing adherence through a Likert scale survey. MMAS-8 has successfully predicted the impact of psychometric factors on MA in various conditions.[12 13] In contrast, Pereira *et al*[5] focused on the relationship between patients and their partners' perception of type 2 diabetes on adherence using the Medicine Adherence Rating Scale (MARS-10). The study highlighted that convergence of patient and partner perceptions improved adherence behaviours, namely self-care activities such as exercise. Furthermore, patients' beliefs or rationale play a key role in MA, as demonstrated in a cross-sectional study in Palestine.[14] The authors used the Beliefs about Medication Questionnaire (BeMQ) in addition to monitoring patient adherence to oral antiglycaemics (n=405). Participants that recognised the necessity of treatment, and who held strong beliefs about their condition were less likely to be non-adherent ($p<0.05$).

Despite cited successes in PROMs determining MA, Martin *et al*[15] highlight the necessity of a multi-faceted approach. Previous comparisons of PROMs that measure the same driver or construct of MA have reported differences in results when measured in the same population.[16–18] Given the breadth of drivers that contribute to MA, the use of PROMs that measure only one specific construct may fail to fully address the extent to which patients take their medicines and the multi-factorial drivers of their behaviour. Despite the current limitations and challenges described in the literature, a holistic tool is yet to be developed, hence the rationale for this project.

SPUR-45 (online supplemental file 1) is a novel multifactorial PROM of MA in type 2 diabetes developed by Observia, an e-health organisation based in Paris. This study aims to examine the SPUR-45 tool and determine the factor and item structure of any revised model prior to an evaluation of the tool's psychometric properties as part of a larger series of international validation studies using the SPUR model. Furthermore, this study aims to explore the relationships between SPUR and socio-clinical factors associated with MA.

RESEARCH DESIGN AND METHODS

A literature review was conducted to identify existing PROMs that explore MA. From the selected questionnaires (n=27), four key domains of MA that constitute the SPUR model, as previously reported by Dolgin,[19] were identified. Each domain covered a specific set of hypothesised drivers of MA behaviours, with 13 drivers extracted in total that were believed to individually and collectively predict MA as an outcome:

- *Social*: subjective norms, interpersonal relationships.
- *Psychographic*: patient–physician relationships, health motivation.
- *Usage*: intention, adherence behaviours/barriers, use, self-efficacy.
- *Rational*: consequence, treatment control and necessity, prevention/harm, knowledge, concerns.

Post-review, suitable items were constructed under each domain by an international research advisory board (n=6). To capture the multifactorial aspects of MA, items were derived for social (n=6), psychographic (n=8), usage (n=13) and rational (n=18) components resulting in the development of the 45-item SPUR-45 questionnaire. Item responses were defined using a 5-point Likert scale denoted as '1—strongly disagree', '2—disagree', '3—niether agree nor disagree', '4—agree' to '5—strongly agree'. Within the questionnaire, 17 items (37.8%) were constructed as negative statements to avoid overexpression of a positive effect direction from participant responses.[20] Likert-scale responses for individual items were totalled (negative statements were reverse coded) for the SPUR tool and divided by the potential total score (5×45) and converted to a percentage score to reflect an overall score for MA. The same method was used for each factor by totalling individual items responses for each subscale with higher scores reflecting a greater likelihood of adherence. Objective adherence is widely reported as a percentage in the literature, hence this approach was taken to improve the interpretability of SPUR scores when compared with these data.

Additional items were included to capture sociodemographic information of participants as well as relevant clinical data such as the number of prescribed antiglycaemic agents and the patients' comorbidities, which were either self-reported or recorded with consent from the medical record (secondary-care arm only). These socio-clinical data were collected to explore expected relationships such as MA increasing with age and income, while decreasing in patients who reported a higher number of prescribed antiglycaemic medicines, comorbidities or body mass index (BMI).

Patient and public involvement

In June 2019, a local patient diabetes support group at Kingston Hospital was sought out for feedback to inform the face and content validity of the developed research materials. Participants (n=15) reported their views on the suitability of survey questions and indicated their experience of poor adherence, recommending the relevance

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of the study. No changes were made to the questionnaire and participants were not involved in the study. However, the researchers agreed to inform patients/public of the outcome of the study. This was completed via the public engagement forums within the Trust. Prior to this patient and public involvement, questionnaire development and pilot testing were conducted with participants (n=60) across the UK, USA, France and China. Participants' feedback at this stage was used to inform the development of the questionnaire, however, the manuscript with these results is currently under review and yet to be published.

Study setting

The study was conducted as a multi-arm, non-interventional, cross-sectional study of patients with type 2 diabetes in England from August 2019 to May 2021. This study has been reported using the Strengthening the Reporting of Observational Studies in Epidemiology cross-sectional checklist.[21] The preliminary arm recruited patients from community pharmacies in Southwest London whereby study procedures were conducted by community pharmacists.

The second arm recruited patients from Kingston Hospital NHS Foundation Trust. Recruitment was conducted by the lead researcher in both the hospital inpatient setting and outpatient endocrine clinics with oversight from the diabetes Clinical Nurse Specialist team. Across both arms, participants were provided with a patient information sheet and written informed consent was obtained prior to completion of the self-administered questionnaire.

Population

Eligible participants were ≥18 years of age, prescribed ≥1 antiglycaemic agent and able to speak English. Participants had a minimum 6-month history of prescribed medications. Excluding factors included participants with significant comorbidities that may affect adherence e.g., active cancer, severe psychiatric illness or registration with another study at the time of recruitment that involved an investigational medicinal product (figure 1).

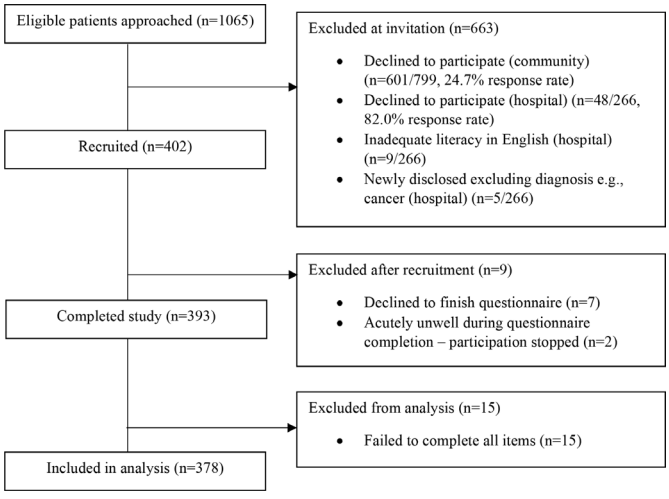

Figure 1 Flow chart of study participant sampling procedure.

Sample size

Raosoft[22] produced a minimum sample size (5% margin of error, 95% CI) based on the number of patients with diagnosed diabetes in the immediate population for Richmond, Kingston and Sutton (n=25 213 patients).[23] The 1:9 ratio of type 1 to type 2 diagnoses was applied (n=22 692) before entry to Raosoft that produced a final minimum sample of 378 patients.

Exploratory factor analysis (EFA) was performed to identify subscales that are represented by grouped questionnaire items. The Kaiser-Meyer-Olkin (KMO) measure of sampling adequacy and Bartlett's test of sphericity were used to determine database eligibility. Visual inspection for an inflection point in scree plots were used to identify initial factors with the addition of Monte Carlo parallel analysis.[24] EFA was conducted to explore the SPUR tool structure in this specific study population using Principle axis factoring with Direct Oblimin rotation, factor loadings >0.3 were considered valid.[25] Inter-factor correlations were observed using Spearman's rho ($p<0.05$).

Cronbach's alpha (α) was calculated as an internal consistency estimate of reliability for both the whole SPUR tool, as well as for individual factors, with an alpha≥0.8 considered as strong evidence of reliability.[26]

Factor and reliability testing were conducted with a view to determine the suitability of the original SPUR-45 tool, or any potential revised model, for further analysis of psychometric properties.

Several previously validated tools that evaluate components of MA were used to examine the convergent and discriminant validity for individual SPUR factors and overall results, namely MARS,[27] BeMQ-Specific and BeMQ-General[28] (examining factors U, R and P, respectively). The MARS (10 items) focuses specifically on MA behaviour such as self-efficacy and was therefore mapped against the usage subscale. The BeMQ-General (8 items) and BeMQ-Specific (10 items) contain subscales related to overuse/harm and necessity/concerns, respectively. The subscales and individual items mapped appropriately to the rational and psychographic factors for the SPUR model and hence were selected as comparators. The 8-item Diabetes Treatment Satisfaction Questionnaire (DTSQ)[29] was included as a comparator for overall adherence/factor scores versus treatment satisfaction. The results of each PROM were determined using the relevant scoring protocols where appropriate. It was expected that higher scores for each PROM for example, high self-efficacy (MARS), high treatment satisfaction (DTSQ) and high perceived necessity (BeMQ-S) and safety of medication (BeMQ-G), would be positively correlated with higher scores for the SPUR tool and the comparative subscale as a strong predictor of MA. It was expected that individual SPUR factors would produce stronger correlations with their comparative PROM than the other tools. These individual assessments of convergent validity

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between PROMs individual factors and overall scores were used to provide evidence of construct validity for the SPUR model.[30] Permission and/or licenses were obtained prior to use of the tools within the study.

Objective clinical data were obtained during the study to examine concurrent validity of SPUR-45, which included HbA_{1c} and the medication possession ratio (MPR). The most recent HbA_{1c} (%, mmol/mol) within the previous 6 months were either self-reported (community arm) or obtained from patients' clinical records (hospital arm). Results of ≤6.5% (48 mmol/mol) for single agent or ≤7.0% (53 mmol/mol) for multi-agent or single hypoglycaemic agent were used to determine adherence. MPR, a crude measure of MA was calculated as a percentage using the formula below:

$$\text{MPR} = \frac{\text{Number of doses prescribed to the patient}}{\text{Number of days within review period (Approx 180 days)}} \times 100\%$$

MPR data were derived from the patient medical record by community pharmacists or the summary care record for hospital participants. An MPR ≥80% was the cut-off for determining a participant as adherent.[31] Spearman's rho was used to test for significant correlations ($p<0.05$) between PROMs, objective data and SPUR. T-tests were conducted to investigate significant differences in mean adherence scores between PROMs and objective measures.

Pearson's correlation analysis was conducted to evaluate the strength and significance of relationships between SPUR and socio-clinical factors to provide evidence of known-group validity. It was hypothesised that MA would significantly increase in tandem with age and income, while decreasing in patients who were prescribed more antiglycaemic agents, reported a greater number of comorbidities or who had higher BMI values. Between-group analyses were conducted to explore significant differences for variables including gender, ethnicity and community versus hospital recruitment on subjective and objective measures of MA. Effect sizes were determined using Cohen's d or Glass's Δ, with the latter reported in instances where SD were significantly different between groups.

All analyses were performed using SPSS V.26.0 for Windows.

RESULTS

The study recruited 378 participants, 178 (24.7% response rate before additional exclusion, n=198/799) and 200 (82.0% response rate before additional exclusion, n=218/266) from the community and secondary-care arms, respectively. Age, education and income were collected as ordinal data and are reported as such. The modal age was 60–69 years (n=96, 25.4%), education was reported predominantly at GCSE level or equivalent (n=122, 32.3%) and more than half the respondents indicated that they were retired (n=196, 51.9%).

The majority of participants were white (n=231, 61.1%). Females represented 40.2% (n=152) of the sample. Where data were available for BMI (n=351/378, 92.9%) mean±SD BMI was 29.35±6.17, indicating that a significant proportion of participants were above their recommended weight. Less than half the sample (n=105/266, 39.5%) met a HbA_{1c} target of ≤7.0% (53 mmol/mol). The mean±SD number of antiglycaemic agents and comorbidities were 1.92±0.90 and 4.70±3.14, respectively (table 1).

Preliminary analysis of factor structure, reliability and model selection

A KMO measure of sampling adequacy was obtained at 0.855 (>0.5). Bartlett's test of sphericity was significant (χ^2=5868.244, $p<0.0001$). Following confirmation of these pre-requisites, EFA was conducted using Direct Oblimin rotation to determine a suitable model for further psychometric evaluation. The initial analysis identified a 13-factor solution for SPUR-45 based on a visual inspection of an inflection point of the scree plot, which explained 62.47% of the variance, however, six items demonstrated factor loadings <0.3. Further Monte Carlo parallel analysis did not support the retention of a 13-factor solution. Iterative scale reduction based on items with loadings <0.3 was conducted to produce a 10-factor solution (n=34 items, KMO=0.868, χ^2=4679.905, $p<0.0001$) that explained 64.23% of the variance.

Internal consistency estimates of the 34-item scale produced a Cronbach's alpha (α) of 0.887 indicating strong reliability of the overall scale. However, several items were identified with item-total correlations (ITCs) <0.3,[32] which led to an increase in reliability (α>0.887) if removed. Further iterative scale reduction based on removal of items with ITCs<0.3 led to a 28-item questionnaire (α>0.899). Items that led to an increase in α scores if removed but with an ITC>0.3 were retained. Further EFA was conducted to examine the factor structure of the new questionnaire. The analysis produced a 7-factor solution (n=28 items, KMO=0.889, χ^2=4015.279, $p<0.0001$) that explained 60.56% of the variance, however, 1-item reported a loading <0.3. On removal, EFA produced a 7-factor solution (n=27 items, KMO=0.889, χ^2=3941.015, $p<0.0001$) that explained 61.85% of the variance with high internal consistency (α=0.900). In summary, EFA conducted on the original SPUR-45 demonstrated a 13-factor model with unacceptably low (<0.3) factor loadings that was unsuitable for further psychometric analysis. The revised 34-item model demonstrated acceptable internal consistency, however, additional iterative item-trimming finally produced a 27-item model with both improved reliability (α=0.900) and a 7-factor structure with acceptable factor loadings across the entire model. The 27-item questionnaire, referred to as SPUR-27 (online supplemental file 2), was chosen for further psychometric analysis given both the greater reliability and variance explained by the model in addition to the overall lower item count.

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Table 1 Study sample characteristics

Parameter	Number (n, %)	Mean±SD	Range	Mode
Age (n=378)				60–69
18–29	3, 0.8			
30–39	8, 2.1			
40–49	42, 11.1			
50–59	58, 15.3			
60–69	96, 25.4			
70–79	94, 24.9			
80+	77, 20.4			
Gender (n=378)				Male
Male	222, 58.7			
Female	152, 40.2			
Other	4, 1.1			
Ethnicity (n=378)				White
White	231, 61.1			
Black	20, 5.3			
Asian	96, 25.4			
Mixed	13, 3.4			
Other	18, 4.8			
Income (n=378)				Retired
<£14 999	30, 7.9			
£15 000–£24 999	42, 11.1			
£25 000–£34 999	31, 8.2			
£35 000–£44 999	30, 7.9			
£45 000–£54 999	5, 1.3			
£55 000–£64 999	5, 1.3			
£65 000–£74 999	1, 0.3			
>£75 000	6, 1.6			
Unemployed	32, 8.5			
Retired	196, 51.9			
Education (n=378)				GSCE or equivalent
No formal education	60, 15.9			
GCSE or equivalent	122, 32.3			
A-level or equivalent	65, 17.2			
Bachelors degree or equivalent	94, 24.9			
Post-grad degree or equivalent	26, 6.9			
Other	11, 2.9			
Clinical factors (n=378)				
BMI (kg/m^2)	351, 92.9	29.35±6.17	14.8–51.0	29.4
HbA_{1c} (%, mmol/mol)	266, 70.4	7.7%±3.9%, 60.29±18.82	28–134	54
Number of antiglycaemics	378, 100	1.92±0.90	1–5	1
Number of conditions	378, 100	4.70±3.14	1–17	4

BMI, body mass index.

SPUR-27 model

Factor 1 (treatment motivation) of SPUR-27 had an eigenvalue of 8.177 (30.26% variance) with five items loading onto the subscale. This was followed by factor 2 (interpersonal relationships) loading three items (eigenvalue=1.971, 7.30% variance), factor 3 (consequence)

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Table 2 SPUR-27 percentage mean scores

Tool/factor (n-items)	Mean score (%±SD)	Range	
		Min	Max
SPUR (27-items)	77.08±12.05	32.40	98.21
F1—treatment plan (P)	84.16±15.22	36.00	100.00
F2—interpersonal relationships (S)	75.42±21.41	20.00	100.00
F3—consequence (R)	73.16±12.19	30.00	87.50
F4—knowledge satisfaction (R)	76.07±20.46	20.00	100.00
F5—adherence behaviours (U)	75.34±17.23	26.67	100.00
F6—control (R)	75.71±18.43	20.00	100.00
F7—ease of use/access (U)	79.71±17.81	20.00	100.00

loading seven items (eigenvalue=1.627, 6.03%), factor 4 (knowledge satisfaction) loading three items (eigenvalue=1.404, 5.20%), factor 5 (adherence behaviour) loading three items (eigenvalue=1.301, 4.82%), factor 6 (control) loading two items (eigenvalue=1.166, 4.32%) and finally factor 7 (ease of use and access) loading four items (eigenvalue=1.053, 3.90%). For each subscale, items aggregated in accordance with the four main SPUR factors from the original 45-item questionnaire (online supplemental file 3). Cronbach's alpha (α) for each factor ranged from 0.561 to 0.818 demonstrating adequate to strong reliability for individual subscales, with ITCs ranging from 0.348 to 0.744. Inter-factor correlations were significant (p<0.01) and ranged from 0.245 to 0.631 (online supplemental file 4).

SPUR-27 score distribution

Each of the 45 items within the original SPUR-45 tool were scored from 1 to 5 with a higher score indicating a greater likelihood of adherence. Most items demonstrated a left-skewed distribution with a range of 2.73–4.45 and 3.72±0.07 total mean score. Overall, 40/45 items (88.9%) reported mean scores between 3.10 and 4.45, indicating similar effects of items on answer responses from participants. None of the positively skewed items (n=3) remained in the SPUR-27 questionnaire following EFA and reliability scale reduction.

The SPUR-27 overall score ranged from 32.40% to 98.21% (mean±SD=77.08±12.05) with 44.7% (n=169/378) scoring ≥80% (table 2). Individual factor total mean scores ranged from 73.16% to 84.16%.

SPUR-27 convergent and discriminant validity

For SPUR-27, average factor loadings were reported as follows: 0.609 (F1), 0.620 (F2), 0.501 (F3), 0.722 (F4), 0.591 (F5), 0.504 (F6) and 0.613 (F7). SPUR-27 demonstrated significant (p<0.01) correlations (r) when comparing total and individual factor scores against other validated PROMs providing evidence of convergent validity (table 3). Notably, when exploring discriminant validity, the SPUR-27 factor 1 score (items derived from the original psychographic domain) correlated most strongly with the BeMQ-S score that was expected to be predictive of the rational domain for the SPUR model. Scores for factors 3–7 (SPUR-27) correlated most strongly with their expected comparative PROMs.

Furthermore, individual factor scores were all significantly correlated with treatment satisfaction as measured

Table 3 Spearman's rho correlations for SPUR-27 versus comparator patient-reported outcome measures

	DTSQ	BeMQ-General (P)	MARS (U)	BeMQ-Specific (R)
SPUR (27-items)	0.647*	0.409*	0.547*	0.639*
F2—interpersonal relationships (S)	0.346*	0.213*	0.250*	0.297*
F1—treatment plan (P)	0.575*	0.287*	0.328*	**0.428***
F5—adherence behaviours (U)	0.504*	0.426*	**0.499***	0.396*
F7—ease of use/access (U)	0.544*	0.370*	**0.417***	0.410*
F3—consequence (R)	0.448*	0.297*	0.426*	**0.612***
F4—knowledge satisfaction (R)	0.503*	0.298*	0.361*	**0.441***
F6—control (R)	0.376*	0.136	0.378	**0.381***

Values highlighted in bold reflect the highest Spearman's rho correlation for each factor when comparing against the BeMQ-General/Specific and MARS
*p<0.01 (two-tailed).
BeMQ, Beliefs about Medication Questionnaire; DTSQ, Diabetes Treatment Satisfaction Questionnaire; MARS, Medicine Adherence Rating Scale.

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Table 4 Spearman's rho correlations between patient-reported outcome measures versus HbA_{1c} and MPR

	HbA_{1c}	MPR
SPUR (27-items)	−0.143*	0.228†
F1—treatment plan (P)	−0.035	0.122*
F2—interpersonal relationships (S)	−0.149*	0.123*
F3—consequence (R)	−0.027	0.168*
F4—knowledge satisfaction (R)	−0.008	0.121*
F5—adherence behaviours (U)	−0.211†	0.161†
F6—control (R)	−0.084	0.215†
F7—ease of use/access (U)	−0.142*	0.209†
Comparator PROMs		
BeMQ-General	−0.135*	0.076
BeMQ-Specific	−0.003	0.157†
DTSQ	−0.104	0.160†
MARS	−0.089	0.209†

*p<0.05 (two-tailed).
†p<0.01 (two-tailed).
BeMQ, Beliefs about Medication Questionnaire; DTSQ, Diabetes Treatment Satisfaction Questionnaire; MPR, medication possession ratio; PROM, patient-reported outcome measure.

by DTSQ, with a strong positive correlation (r≥0.6) observed for the overall SPUR-27 score (r=0.647).

SPUR-27 concurrent validity

Objective clinical data were collected to examine the concurrent validity of SPUR-27 (table 4). SPUR-27 was significantly correlated with both HbA_{1c} (r=−0.143, p<0.05) and MPR (r=−0.228, p<0.01) when analysing the total questionnaire score. In descending order, significant correlations were also observed individually between HbA_{1c} and factor 5 (r=−0.211, p<0.01), factor 2 (r=−0.149, p<0.05) and factor 7 (r=−0.142, p<0.05) which represented subscales for social and usage domains of the original SPUR model. All factors reported significant weak correlations to MPR with a range of 0.121–0.215. SPUR-27 was also able to distinguish between patients with poor glycaemic control (HbA_{1c}>7.0, n=161/266, 60.5%) versus optimal glycaemic control (HbA_{1c}≤7.0, n=105/266, 39.5%) when comparing mean total scores (77.6% vs 80.5%, p<0.05). Moreover, when comparing mean total scores for patients with low MPR adherence (MPR<80%, n=68/378, 18.0%) and high MPR adherence (MPR≥80%, n=310/378, 82.0%), the same result was observed (73.3% vs 77.9%, p<0.01). Of the comparators, only the BeMQ-General tool observed a significant correlation with HbA_{1c} (r=−0.135, p<0.05). Furthermore, when evaluating the ability of the comparator PROMs to distinguish between poor versus optimal glycaemic control, only the DTSQ produced a significant result (p<0.05). In conclusion, SPUR-27 was significantly correlated to both objective measures of adherence and consistently able to distinguish groups of patients based on their levels of adherence providing initial evidence of concurrent validity in this sample.

SPUR-27 known group validity

As hypothesised, positive significant correlations were observed when comparing SPUR-27 scores with age (r=0.354, p<0.01) and income (r=0.303, p<0.01). Negative significant correlations were observed when comparing SPUR-27 scores with BMI (r=−0.163, p<0.01) and the number of prescribed antiglycaemic agents (r=−0.139, p<0.05). In contrast to our initial hypothesis, the number of comorbidities was positively correlated to SPUR-27 scores (r=0.246, p<0.01).

No significant difference in SPUR-27 mean score was observed for participants based on their reported gender (p=0.84, 95% CI −2.23 to 2.75, Cohen's d=0.02). The largest difference in SPUR-27 mean score based on ethnicity was observed between white (n=231, 80.83±0.77) and black (n=20, 73.94±2.62) participants, however, this finding was not significant (p=0.18, 95% CI −1.13 to 12.11, Glass's Δ=0.40). When comparing recruitment arms, community participants reported a significantly lower SPUR-27 mean score than those in the secondary-care arm (73.15 vs 80.58, p<0.0001, 95% CI 5.07 to 9.78, Glass's Δ=0.65) indicating lower self-reported adherence. A significant result (p<0.01, 95% CI 1.97 to 9.60, Glass's Δ=0.32) was also observed when analysing HbA_{1c} mean scores for the community arm (n=70/266, 7.3%, 56.34±11.00 mmol/mol) and the secondary-care arm (n=196/266, 7.8%, 61.69±19.89 mmol/mol).

DISCUSSION

This study aimed to examine the SPUR model as a multifactorial PROM of MA in type 2 diabetes, in addition to exploring relationships between the model and socio-clinical factors associated with MA. Factor and reliability analyses were conducted using the original SPUR-45 tool to identify a suitable model for further psychometric analysis. As a result of the analysis, a revised and more concise model referred to as SPUR-27 was identified. The data support encouraging early results for the psychometric properties of the revised SPUR-27 model as well as demonstrating significant relationships with predicted socio-clinical factors.

EFA was conducted with the intention of exploring and understanding the structure of the overall SPUR model. SPUR-27 was derived from an iterative approach to model refinement through factor analysis, reliability testing and item-trimming. The 7-factor solution identified sub-scales that aggregated within, and were reflective of, all four of the original SPUR-45 domains with acceptable factor loadings across the entire model. The SPUR-27 factors mapped to seven of the 13 previously hypothesised drivers of MA within each major domain as previously highlighted by Dolgin.[19] SPUR-27 reported high internal consistency (α=0.900) with fewer items compared with SPUR-45.[26]

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Building on both the EFA and reliability analysis, mean total and individual factor scores for SPUR-27 were assessed. Using a ≥80% cut-off as a measure,[31] SPUR-27 reported sample adherence at 44.7% (n=169/378), closely reflecting HbA_{1c} adherence at 39.9% (n=106/266) for those participants where data were available. Further assessment of the sample based on MPR data indicated that 82.0% of participants were adherent (MPR≥80%, n=310/378). Although not unexpected, given the tendency of MPR to over-estimate adherence,[33] the large variation in adherence outcome based on objective data was surprising. Anecdotally, pharmacists conducting the study reported less contact with patients given that recruitment took place during the COVID-19 pandemic. Medicines were delivered to patients' homes without face-to-face engagement, reducing the capacity for adherence interventions which may have resulted in poorer HbA_{1c}. However, medicines were still dispensed and hence would contribute to a positive MPR, leading to highly exaggerated MPR scores among this cohort. Quantifying the impact of COVID-19 on medicines use and access to diabetes care is challenging, however both within the UK and internationally, the literature indicates that people living with type 2 diabetes have been disproportionately affected by the pandemic.[34 35] The authors therefore encourage readers to bear this in mind as a potential variable when considering the results of this study.

Given the absence of a current gold standard measure, previous work has recommended the use of multiple measures of adherence to improve the reliability of results.[16 36] The original SPUR-45 encompassed multiple measures within a single tool, hence four additional PROMs were chosen as comparators for this study. The revised SPUR-27 produced fair (≥0.3–0.59) to moderate (≥0.6–0.79) correlations for total scores and individual factors when compared against the corresponding PROM.[37] The only outlier was factor 1 for SPUR-27 (0.287) with a weaker correlation, however, the overall domain score was acceptable (0.409). Moreover, this SPUR-27 subscale produced the strongest correlation with the DTSQ score (r=0.575), indicating that overall treatment satisfaction may have been more impactful than the physician–patient relationship alone in determining adherence, although both have been demonstrated as synergistic in their capacity to improve MA in type 2 diabetes.[38] Using the multi-PROM approach, the study has provided good initial evidence of convergent validity for SPUR-27 in this sample.

It was predicted that individual factors would be most strongly correlated with their designated comparator PROM, for example, usage subscales versus MARS, to provide evidence of discriminant validity. The results were predominantly concordant with these predictions except for factor 1 (treatment plan), which observed stronger correlations with BeMQ-S (comparative tool for rational domain). SPUR was designed as a holistic model, hence, determining discriminant validity based on other comparative PROMs that measure specific constructs may be limited, however, this finding warrants further exploration with additional sample populations to provide conclusive evidence of discriminant validity for the SPUR-27 model.

Known group validity was determined for age, income, BMI and number of antiglycaemic as expected, however the number of comorbidities was an outlier with a positive correlation to adherence. Briesacher *et al*[39] reported similar findings. Although not completely clear, causality could in part be attributed to higher use of healthcare resources among those with greater comorbidity, particularly during the pandemic where the more complex patients were seen face-to-face, which may affect MA. Furthermore, the COVID-19 'vulnerable' status applied to type 2 diabetes, hence patients may have been more cognisant of their risk, therefore leading to increased adherence.

SPUR-27 was the only measure to distinguish between grouped adherence patterns for both HbA_{1c} and MPR. Although SPUR-27 reported weak correlations (<0.3), it was the only tool in addition to the BeMQ-General that produced a significant outcome. Furthermore, SPUR-27 reported the highest correlation to HbA_{1c} and MPR of any PROM included in the analysis. One possible explanation may be offered by Holland *et al*[40] in their recent assessment of HbA_{1c} test uptake during the pandemic. The authors report a reduction to HbA_{1c} testing of 82%–88% post the initial March 2020 lockdown. Three-monthly interval HbA_{1c} testing has previously been associated with a 3.8% reduction in HbA_{1c}, compared with a 1.5% increase observed with annual testing.[40] Therefore, there may be some disparity in perceived self-management, particularly MA, that does not equate with actual adherence reflected in measures such as HbA_{1c}. However, it is encouraging that despite this shift in testing uptake, SPUR-27 could still detect significant variations in HbA_{1c}. Alternatively, it is important to consider the role of diet and exercise on HbA_{1c}, both of which have been negatively impacted by lockdown.[41] To this extent, patients that do not maintain usual self-care through diet and exercise but continue to take their medicines regularly may still be subject to sub-optimal HbA_{1c} values that do not completely correlate with self-reported MA, which was consistent across the PROMs in this study. Moreover, social desirability bias and discrepancies in self-reported HbA1c have not been fully considered for this study. Those recruited from the community arm are more likely to report an incorrect HbA1c value based on their memory versus HbA1c data that were extracted directly from the medical records for patients from the hospital arm. Hence, this is a potential limitation to quantifying true correlations between self-report and objective measures that future work should look to address.

Another notable limitation includes the lack of test–retest reliability data. Despite integration of re-testing into the original protocols, the pandemic prevented suitable follow-up. The risk to patients returning for follow-up outweighed the potential benefit of re-testing

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in this sample, therefore the authors recommend that test–retest analysis be conducted in future studies with the SPUR model. It is also pertinent to recognise the over-representation of male participants in this study, accounting for almost 60% of the total sample. Assertions of evidence for validity with respect to psychometric properties of SPUR-27 for this study are therefore based on a predominantly male sample, which may not consider gender-specific biases to certain items. However, it should be noted that no statistically significant difference was observed when comparing SPUR-27 mean adherence scores by gender in this study. This study also employed techniques such as Monte Carlo parallel analysis to explore the factorial structure of the SPUR model. This approach has been associated with over-factoring of models, however, the authors emphasise that this study is reflective of only one specific sample of participants with limited scope to discuss replicability at this stage, hence, results should not be considered as conclusive with respect to validity.[42] Further work is needed across different samples in order to ensure the results are truly meaningful for participants living with type 2 diabetes.

The study has several strengths that have supported the primary outcome of providing early evidence of psychometric properties for the SPUR-27 model. First, the inclusion of numerous PROMs to compare against the multifactorial SPUR-27 questionnaire that provided empirical data for construct evaluation. Second, two objective adherence data sets were used to demonstrate concurrent validity with not only the novel PROM, but previously validated tools that provided greater insight into the influence of numerous adherence behaviours on clinical outcomes such as HbA_{1c}. Finally, EFA and reliability testing produced a more concise tool, SPUR-27, which provided early evidence of psychometric properties for this sample population. To our knowledge, this is the first study to demonstrate the psychometric properties of a PROM of MA in type 2 diabetes that encompasses four major domains of adherence behaviour within a single tool.

Future work should look to build on the assessment of psychometric properties as part of a validation analysis using methods such as Item Response Theory and Structural Equation Modelling. Furthermore, the transferability of the tool should be evaluated using alternative chronic conditions, for example, chronic obstructive pulmonary disease/asthma or different target languages to improve the availability of SPUR models for future adherence studies.

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Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not applicable.

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