




# BMJ Open First use of Simulation in Therapeutic Patient Education (S-TPE) in adults with diabetes: a pilot study

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## ABSTRACT

**Objective** To pilot test the feasibility and acceptability of Simulation in Therapeutic Patient Education (S-TPE), in both adult patients with diabetes and educators.

**Conception** Adult patients with insulin-dependent diabetes and who participated in a full TPE programme for the implementation of a FreeStyle were included in this monocentric pilot study. S-TPE intervention was based on a consensus conference determining the conditions and objectives of S-TPE. Main outcomes were the patients' and educators' perception of the usefulness of S-TPE and the patient's satisfaction level at the conclusion of the simulation sequence, measured on validated scales. Secondary outcomes were organisational, human, material and temporal, facilitating and limiting factors for patients and educators, patient self-efficacy and anxiety scores.

**Interventions** The final session of TPE used the simulation. For each group, one patient volunteered to be the simulated patient. Intervention was divided into three steps: (1) a pre-briefing, (2) a simulation of hypoglycaemia and (3) a debriefing with the group of patients and educators. The whole intervention lasted about 2 hours.

**Results** We included 23 patients (mean age  $\pm$ SD 63 $\pm$ 15 years, 14 men) and 3 educators. After S-TPE intervention, patients' and educators' perceived usefulness score were 20.6/25 and 37.5/40, respectively. Patient's satisfaction score was 51.9/60. Qualitative analysis revealed no limiting factors to implementing S-TPE. Self-efficacy was stable. Decrease in anxiety score after S-TPE reached statistical significance in women (from 35.1 $\pm$ 4.5 to 32.7 $\pm$ 5.5,  $p=0.04$ ) but not in men.

**Conclusion** No limiting factors that could prevent the conduct of clinical trials to assess S-TPE efficacy in patients with diabetes were identified. S-TPE appears as a promising technique to improve diabetes management.

**Trial registration number** Registration N°: 2019-A00773-54 and NTC: 03956927.

## INTRODUCTION

Therapeutic patient education (TPE) administered in a hospital or community context helps chronically ill patients to develop self-care and daily life skills within the constraints imposed by the disease.<sup>1,2</sup> TPE has met the needs of patients with diabetes,<sup>3</sup> asthma<sup>4</sup> and heart failure.<sup>5</sup> Patient benefits include greater

## Strengths and limitations of this study

- This pilot trial is the first to study the feasibility and acceptability of Simulation in Therapeutic Patient Education (S-TPE) in both patients and their helpers.
- S-TPE method used in this study is a standardised intervention based on the recommendations of an expert consensus conference.
- Evaluation was not limited to self-efficacy outcomes but also assessed patients' satisfaction.
- The absence of a control group did not permit to study preliminary efficacy outcomes.
- The limited number of patients did not provide enough power to quantify the benefit of S-TPE on self-efficacy.

compliance, fewer complications, higher quality of life and an increase in perceived health status.<sup>6</sup> TPE reduces hospital stays and costs,<sup>7,8</sup> but there are not enough trained educators, especially in remote areas.<sup>9</sup> Most TPE programmes only offer instruction but neglect skills necessary for everyday life.<sup>10–12</sup> Some self-care skills may be difficult to acquire during TPE, including managing uncontrolled and severe hypoglycaemia.<sup>13</sup>

The current evaluation of TPE's contribution to healthcare in patients with diabetes may be too narrow and inadequately captures its effects. In a systematic review of TPE for type 1 diabetes, Fonte *et al*<sup>10</sup> concluded that studies are too focused on clinical, biological and economic outcomes and often failed to measure psychosocial or coping skills, for which patients must acquire social and practical skills to cope with chronic illness. Unfortunately, no validated teaching method both instructs patients in the necessary skill set and ensures that they can use those skills in daily life.

If TPE training was combined with simulation, patients might find it easier to develop real world coping skills. Simulation provides



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a structured learning environment in which patients can learn to handle real word situations and develop their skills and abilities without imposing ethical, economic or technical risks.<sup>14</sup> Simulation improves self-efficacy in parents caring for children with diabetes and children leaving neonatal care.<sup>15 16</sup> Simulation develops skills in professionals but is not yet integrated into TPE.<sup>14</sup> Whether simulation would extend the benefits of TPE is a matter of debate. Coleman<sup>17</sup> advocated its use because it was successful in training programmes for health professionals, but Lefèvre *et al*<sup>18</sup> thought Simulation in Therapeutic Patient Education (S-TPE) may be too complicated for patients and could present difficulties for multimorbid, low literacy, or fragile patients.

We thus designed this pilot study to determine if S-TPE was feasible and acceptable to patients and educators and to identify facilitators or barriers to its incorporation into routine TPE practice. We also aimed to ensure that the simulation was accessible to carers carrying out TPE and that the methods and means were accessible to them. This research is essential in order to enable a multi-centre trial to be carried out afterwards to study the effects of this S-TPE on patients.

## METHODS

### Study population

The study population included adults with type 1 or 2 diabetes who needed insulin and diabetes educators in charge of TPE at their institution. The criteria for inclusion were as follows: to be of legal age, to have given their unopposed consent and to be insulin-dependent diabetic who had participated in a full TPE programme (three sessions) for the implementation of a Free Style Libre. The exclusion criteria were as follows: to be subject to a legal protection measure (curatorship, guardianship) or the subject of a legal safeguard measure or to be of legal age and incapable or unable to express consent. Patients, drawn at random from the list of eligible patients and then contacted by telephone, were enrolled between March and June 2019 at Dijon Bourgogne University Hospital. They received the protocol in the mail, and then the educator explained the study over the phone. All participants provided written informed consent before starting the trial. All educators trained in diabetes patient therapeutic education were eligible for the trial and provided informed consent.

### Outcomes

Our two primary outcomes were (1) the patients' and educators' perception of the usefulness of S-TPE and (2) patient satisfaction level at the conclusion of the simulation sequence. Our secondary outcomes were (1) change in patients' S-TPE self-efficacy score (pre to post), (2) patients' anxiety scores and (3) organisational, human, material and temporal facilitating and limiting factors for patients and educators.

To obtain these outcomes, we administered a series of five questionnaires to patients and two to educators. Ahead of the S-TPE session, the following questionnaires were given to patients only, to measure their baseline score:

- ▶ Self-efficacy was measured by the self-administered Schwarzer General Self-Efficacy Scale (GSES),<sup>19</sup> which we adapted to patients who wear a continuous interstitial glucose metre (online supplemental appendix 1).
- ▶ Anxiety was measured by the validated French translation of the State and Trait Anxiety Inventory (STAI).<sup>20</sup> The STAI contains two questionnaires, one measuring the respondent's usual emotional state (trait anxiety questionnaire—STAI-Y1) and one measuring their situational anxiety (state anxiety questionnaire—STAI-Y2). Each questionnaire includes 20 items to be rated on a 4-point Likert scale ('almost never' to 'almost always') (online supplemental appendix 2). The level of a patient's nervousness and anxiety during the S-TPE session was determined by their score on the STAI-Y2 questionnaire. Score thresholds are detailed in online supplemental appendix 2.

At the end of the S-TPE session, the following questionnaires were administered to patients and educators, or patients only:

- ▶ The GSES and STAI-Y2 were re-administered to patients only, to obtain post-intervention scores for self-efficacy and situational anxiety.
- ▶ A self-administered questionnaire, scored on a 5-point Likert scale from 'strongly disagree' to 'strongly agree', was given to patients and educators, to measure their perception of S-TPE's usefulness. The patients' questionnaire contains four items (online supplemental appendix 3) and the educators' eight items (online supplemental appendix 4).
- ▶ Patients completed a self-administered satisfaction questionnaire (online supplemental appendix 5) that contained 12 items, scored on a 5-point Likert scale from 'strongly disagree' to 'strongly agree'. Based on level I ('Evaluation—Reaction') of Kirkpatrick's global model for evaluating training courses,<sup>21</sup> and on criteria for measuring the quality of therapeutic education,<sup>7</sup> this questionnaire incorporated the following elements: objectives, expectations, progression, questioning, method, place, duration, quality of the exchanges with the participants and professionals, and recommendation to another person.
- ▶ A final self-administered questionnaire administered to patients (online supplemental appendix 6) and educators (online supplemental appendix 7) containing three open-ended questions on the organisational, human, material, temporal, facilitating and limiting factors of S-TPE and areas for improvement.

To improve and deepen the transcripts of responses to the three open-ended questions, an investigator (CP) conducted a semi-directed follow-up phone interview 15–30 days after the S-TPE session.

### Box 1 Skills for which simulation brings added value to therapeutic patient education (10 statements)

- ▶ D1: Simulation is recommended for learning to cope with unusual/infrequent situations.
- ▶ D2: Simulation is recommended for developing communication skills.
- ▶ D3: Simulation is recommended for promoting the integration of new technologies in disease self-management.
- ▶ D4: Simulation is recommended for promoting partnerships between the care team and the patient for his/her own health or as an expert patient.
- ▶ D5: Simulation is recommended for learning to cope with stress.
- ▶ D6: Simulation is recommended for reinforcing the feeling of self-efficacy.
- ▶ D7: Simulation is recommended for learning how to adjust treatment.
- ▶ D8: Simulation is recommended for learning how to manage a crisis or emergency.
- ▶ D9: Simulation is recommended to learn to involve the social network in care.
- ▶ D10: Simulation is recommended for increasing the motivation to take care of oneself.

#### Skills covered by the S-TPE session

We based our trial on S-TPE recommendations made by a group of 25 TPE and simulation experts and expert diabetes patients who came to consensus at a conference in December 2017.<sup>22</sup> They recommended 10 objectives and specified learner characteristics, conditions of use and ethical conditions (box 1).

We set up the pilot to test these objectives: ‘use simulation to promote integration of new technologies into self-management of diseases’ and ‘use simulation to show patients how to manage a crisis or emergency’. The simulation was developed by educators, including two nurses and a doctor in charge of the TPE, the nurse in charge of the diabetology department, a TPE expert and the three people responsible for simulation training at our institution, two of whom were trained in both TPE and simulation. The educators decided to incorporate three more objectives that can be described as ‘taking the proper steps when faced with hypoglycaemia’: (1) ‘identifying possible signs of hypoglycaemia to initiate appropriate management’; (2) ‘interpreting the screen data of the continuous interstitial glucose metre’ and (3) ‘how to act in cases of hypoglycaemia’.

The educators ran through the simulation three times to accustom themselves to pre-briefing and debriefing patients who might have different reactions.

#### Description of S-TPE

Standard TPE comprises four sessions where two or three trained physicians or nurses teach up to 10 patients. The educators conducted a single session with each group of patients. One patient simulated and the others observed. Our S-TPE were led by a trained health professional who had been practicing TPE for at least 3 years. At the beginning of the S-TPE session, a research technician

administered the three pre-intervention questionnaires to patients.

We held three S-TPE sessions, of seven, nine and eight patients. Patients attended one S-TPE session. In each session, one patient was asked to volunteer to be the ‘simulating’ patient; they were filmed and broadcasted to the other patients who observed in a nearby room. Simulating patients were pre-briefed on the scenario and played the scene as if they were at home in a standardised room. They simulated hypoglycaemia and acted after an interstitial glucose reading. Post-simulation, all patients debriefed together. We used one simulating patient per group because participants and observers benefit equally.<sup>23</sup>

The S-TPE session had three phases:

1. A nurse led the *briefing phase* that familiarised patients with material, context, confidentiality, ethics rules, instructions and expectations for the simulation. Educators instructed patients to, above all, be kind to one another and to suspend judgement and guaranteed this behaviour. The simulating patient was also briefed on the scenario and paraphrased it to ensure they understood. The patient was told educators would intervene if they deviated from the scenario, in the form of a visit during the simulation.
2. In the *scenario phase* (scenario), the simulating patient’s performance was guided by the trainer.<sup>24</sup>
3. All educators and patients participated in the steps of the *debriefing phase*: description, analysis, synthesis (table 1). Then, patients and educators filled out post-intervention (section Outcomes). The intervention followed the methodology recommended by the experts in their consensus conference.<sup>22</sup> TPE sessions always remained focused on the objectives of the session, that is, here the management of hypoglycaemia with an interstitial glucose metre, as well as the recognition of the signs of hypoglycaemia, glycaemic corrective actions and the particularities of continuous interstitial glucose reading. Everything was planned in the guide written for the session so all three groups received the same education. Online supplemental figure 1 shows the process of this research.

#### Statistical analysis

Our primary analysis was based on data provided by patients who answered the study questionnaires. We used descriptive statistics to characterise the patients’ socio-demographic characteristics and expressed quantitative variables as numbers and percentages. Quantitative variables were reported as means and their SD, with minimum (min) and maximum (max) value for scores. We used a  $\chi^2$  test or Fisher exact test to compare qualitative variables pre-intervention and post-intervention. We compared means with a Student t-test for matched pairs or a Wilcoxon signed-rank test after we determined distribution. For all tests, we considered  $p < 0.05$  significant. SAS V.9.4 was used for all analyses.

**Table 1** The three-phase methodology for simulation

Briefing	Familiarises patients with the material and the context. Caregivers explain the rules of confidentiality and deontology and give instructions for the exercise, stating their expectations. The instructor tells participants that the most important rule is to be kind to one another and not pass judgement.
Scenario	Performed by learners and guided by the instructor: 'the instructor makes constant adjustments to the scenario to keep the learners in a problem-solving situation. If necessary, the instructor can intervene personally or through a facilitator to help the learners'.
Debriefing	Gives patients time to analyse and synthesise their experience. In the <b>descriptive phase</b> , patients can describe their impressions and then express emotions and feelings. In the <b>analysis phase</b> , patients are encouraged to explain why they acted as they did. In the metacognition phase, patients are encouraged to explore their reasoning without being judged. Observers can also respectfully express their views on the actions and choices of other participants, each presenting their own arguments. In the final synthesis phase, which takes up what the patients have learnt, the instructor encourages them to formulate the changes that their new knowledge and skills may make in their lives.

In our qualitative analysis, we organised and interpreted the narrative data, both written and transcribed (see paragraph Study population), to identify themes and create reference categories.<sup>25</sup> One person (CP) condensed the data and coded it to assign keywords. CP extracted in vivo quotes, characterised them with keywords, sorted them into categories and then derived themes from the categories. We then described different dimensions and identified barriers and facilitators of S-TPE to determine which factors would need to be modified or maintained for a large-scale efficacy trial. Our analysis adhered to the Standards for Reporting Qualitative Research (SRQR).<sup>26</sup>

The primary objective of this non-randomised study was to estimate the feasibility and acceptability of S-TPE. The sample of 24 patients was based on the estimate of Hennink *et al*<sup>27</sup> that 16–24 qualitative interviews generally achieve saturation. No formal sample size calculation was performed.

### Patient and public involvement

Patients and/or the public were involved in the consensus conference that paves this work as well as in the construction of the simulation and the design of the study. Information on the publication of this study will be provided to the patients on the website (<http://www.chu-dijon.fr>) and the social networks of our hospital.

## RESULTS

### Patients' description

In total, 24 patients were included in the study. One patient was wrongly excluded since he was not wearing an interstitial glucose reading device, and thus was quickly excluded (see [table 2](#) for characteristics).

Wearing an interstitial glucose reading device was an inclusion criterion, and a patient was thus quickly excluded because he was not wearing the device. The 23 participants were 63±15 years old, with a 29.5±15-year history of diabetes. Among them, 18 (78%) had comorbid conditions: 4 (17%) had thyroid disorders; 13 (57%) had cardiopulmonary disorders; 13 (57%) had miscellaneous disorders; 10 (43%) had diabetes-related

disorders and 5 (21%) were deemed as more than 70% disabled according to the definition of the French social security rating.

### Result of the main analysis in patients and educators

Patients found S-TPE to be very useful (mean score 20.6±3.5 for a maximum of 25) and expressed high satisfaction at the end of the session (mean 51.9±4.9 for a maximum of 60) ([table 3](#)). Perceived usefulness of S-TPE was also high among educators, whose scores increased after each session (30.6±5.8, 36±1.4 and 37.5±3.5 for sessions 1, 2 and 3, for a maximum, respectively; for a maximum of 40) ([table 3](#)).

### Result of secondary analysis in patients and educators

Our analysis of post-S-TPE phone interviews with patients identified these characteristics of S-TPE: [tables 4 and 5](#)

**Table 2** Population characteristics (n=23)

Population characteristics	(n=23)
Age (years), (mean±SD)	62.8 (14.9)
Duration of illness (years), (mean±SD)	29.5 (15)
Sex—male, n (%)	14 (60)
Level of education, n (%)	
Elementary	5 (22)
College	7 (30)
High school	8 (34)
Post-baccalaureate	3 (14)
Concomitant comorbidities, n (%)	
Diabetes-related (renal vascular, ophthalmologic)	10 (43)
Thyroid disorders	4 (17)
Cardiopulmonary (MI, hypertension, chronic bronchitis)	13 (57)
Other	13 (57)
Recognised disability >70%, n (%)	5 (21)
MI, myocardial infarction.	

**Table 3** Results of the satisfaction, anxiety utility and self-efficacy questionnaires (n=23)

Questionnaires	Patient satisfaction /60	Perceived usefulness to patients /25	Perceived usefulness to caregivers /40	STAI-Y1	STAI-Y2 Before	STAI-Y2 After	P value*	Self-efficacy before /40	Self-efficacy after /40	P value†
Score obtained (mean±SD; min-max)										
General population of patients	51.9 (4.9; 41–60)	20.6 (3.5; 9–25)	37.5 (3.5; 28/40)	35.5 (6.9; 22–49) 36.1 (4.8; 29–45)	34.2 (7.8; 21–46) 35.1 (4.5; 29–43)	32.1 (5.2; 22–45) 32.7 (5.5; 27–44)	0.17 0.04	35 (3.3; 27–40)	35.6 (3.0; 28–40)	0.29
Ment										
Women‡										

\*P value for comparison between STAI-Y2 scores before vs after S-TPE.

†P value for comparison between self-efficacy scores before vs after S-TPE.

‡For STAI-Y1: absence of anxiety is defined by a score <39 for men and <47 for women; for STAI-Y2: absence of anxiety is defined by a score <37 for men and <42 for women. STAI-Y1, state anxiety questionnaire; STAI-Y2, trait anxiety questionnaire; S-TPE, Simulation for Therapeutic Patient Education.

summarise the results for each group and by theme with samples supporting quotes.

All patients expressed their overall satisfaction (23/23), to the point of stating that ‘It allowed me to modify my practice’. When asked about technical improvement, they could suggest the following, two patients suggested that the sound should be improved, one of them also stated that he/she did not want the session to last more than 2 hours and the other one reported difficulty in expressing himself/herself in front of the group. When asked about the potential improvements to be made, 19 patients (82.6%) did not express a need for changing the technique, one patient suggested doing more different sessions and one expressed he/she would like to review the objectives.

The remaining 21 did not suggest anything to improve.

Benefits of the S-TPE expressed by the patients were as follow: the relationship skills (7/23, 30.4%), ‘The exchanges, the relationships with the other participants are richer’; the pedagogical qualities (15/23, 65.2%), ‘It’s more concrete, it allows you to approach problems in different ways’ and the effects on daily life (8/23, 34.8%), ‘I’ve changed, something clicked,’ ‘I know now’. ‘This method removes certain beliefs’ (see table 4).

Our analysis of post-S-TPE phone interviews with educators identified these points: ‘development of coping skills (not feeling alone, gaining self-confidence, managing stress, talking about one’s illness)’; ‘a complete overview of the issue (hypoglycaemia in this case) and is used in all its dimensions’ and ‘concrete, speaking, explicit, it’s living for them, they recognised themselves in the situation’. One participant called it ‘very positive’: ‘I would’ve surrendered at first, but now I’d do it again. It’s an immense satisfaction, a lot of fun. I’ve learned a lot. It was very rewarding to use a new method, to share this’ (see table 5).

All (3/3) educators were very satisfied with the method overall. Even though it was considered stressful and requiring skill development, they were willing to try it again. S-TPE improved relational skills for all educators (3/3) and two of them stated that this method can be used in patients with physical disabilities or not fluent in French. Two out of three educators also reported the sound quality to be suboptimal. All the educators noted the pedagogical interest of the method and the good quality of the relationship with the group. The exchanges have been improved and enriched, thanks to this method of S-ETP. They report that ‘a complicity has appeared, there is a better mutual acquaintance’. The groups should be of a maximum of eight people, because with family carers it can quickly become difficult to manage. All educators noted that S-TPE is relevant with patients, ‘Relevant teaching method: it’s a fun method that appeals to all the senses: visual, auditory, kinaesthetic. This method allows each person to express themselves, their daily life, they were able to communicate, exchange’. One educator noted that the final synthesis could be improved and that it is necessary to ensure that the objectives are those of the patients.

**Table 4** Analysis of responses to open-ended questions from post-TPE patients (n=23)**General perspective on S-TPE**

Positive considerations (23/23)	Technical Improvements (2/23)
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'It allowed me to modify my practice', 'I liked the exchanges', 'I want to do it again', 'it was interesting'...	'Work on the hardware and its technical features'
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**Limitations on the use of S-TPE**

Positive consideration (21/23)	Improvement relating to duration (1/23)	Improvement in group expression (1/23)
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'None', 'nothing'	'A little long, no more than 2 hours'	'Too many people, not easy to express yourself in front of others'
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**Benefits of using S-TPE**

Relationship skills (7/23)	Pedagogical qualities (15/23)	Effects on daily life (8/23)
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'The exchanges, the relationships with the other participants are richer'	'It's more concrete, it allows you to approach problems in different ways'	'I've changed, I've clicked', 'I know now. This method removes certain beliefs'
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**Suggested improvements to the use of S-TPE**

None (19/23)	Proposal on other topics (1/23)	Technical improvement (1/23)	Related to the objectives of the session (2/23)
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'nothing, it was fine'	'Do different sessions either in a theme day or by varying situations'	'The sound reasoned a little'	The groups should be 'better at the onset of the disease', 'that the groups should be level'
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S-TPE, Simulation for Therapeutic Patient Education.

Two educators noted that 2 hours was the optimal duration for the session, which should neither be reduced nor be exceeded.

Two training sessions were initially scheduled, but extended to three sessions as per educators' request. In the post S-TPE session phone interviews, educators said that they needed five to eight sessions to become fully comfortable with the method.

S-TPE did not change patients' self-efficacy score (35.6±3 points pre-S-TPE vs 35.3±3 points post-S-TPE,  $p=0.29$ ) (table 3). The STAI-Y1 (anxiety status assessment) scored showed that 13.0% (3/23) of patients (all men) had an anxious personality. The STAI-Y2 (anxiety trait) showed that anxiety scores dropped significantly after S-TPE in women (35.1±4.5 pre-S-TPE vs 32.7±5.5 post-S-TPE,  $p=0.04$ ), but not in men (34.2±7.8 pre-S-TPE vs 32.1±5.2 post-S-TPE,  $p=0.17$ ) (table 3).

**DISCUSSION AND CONCLUSION**

We identified no barriers to implementing a trial to assess the value of an S-TPE programme for adults with diabetes. Our study suggests that S-TPE may decrease patient anxiety, though this finding was statistically significant only for women. On average, patients ranked S-TPE as very useful (20.6/25), with only one patient scoring its usefulness as low (12.5/20). Patient satisfaction at the end of the S-TPE session was high (51.9±4.9/60).

Patients unanimously approved of the approach and said it created a favourable climate for learning and gave them opportunities to talk about problems in their daily life. They appreciated the structured approach, which allowed everyone to express themselves. They felt that the simulation helped them understand the effects of their disease-related behaviours without putting themselves at risk.

The overall positive reception of S-TPE is encouraging. The only patient who ranked the usefulness of S-TPE as low appeared to prioritise hyperglycaemia rather than hypoglycaemia management (table 4). S-TPE appears to meet the needs of patients with different backgrounds. Two patients in our study were not native French speakers, one had a hearing impairment and another a walking disability; all found S-TPE helpful.

Interviews with educators revealed their fear and stress in the first session and the desire to perform well. They said that their stress lessened during the sessions and that they are now focusing on managing group dynamics, for example, paying attention to each patient and animating patients rather than just transmitting information. Educators asked many questions and said they need five to eight S-TPE sessions before they would feel comfortable implementing the method (table 4).

Our pilot study was limited in the following ways: its small sample size (23 patients) limits our ability to generalise findings to the target population of adult patients

**Table 5** Analysis of responses to open-ended caregiver questions

Questions	Relationship skills	Technical improvements	Pedagogical qualities and team work	Improvement relating to duration
<p>Right after the S-TPE 'Describe in a few words what you've appreciated in this TPE session'.</p> <p>'Describe in a few words what may have bothered you in the TPE session'.</p> <p>'How could this TPE session be improved?'</p> <p>At a distance from the session: 'What would you like to say about the sessions that used the simulation today?'</p>	<p>'Cooperation and collaboration with all stakeholders. 3/3</p> <p>The good mood of the group the participation' 3/3</p> <p>'Patients' attention, yet relaxed; their participation'.</p> <p>'A lot of stress and finally it has a good time'.</p> <p>'It was necessary to work personally, a beautiful discovery, an interesting, intense, fascinating and very fun method for the patients. I've learned a lot. The teamwork was very rich. A complicity has appeared, there is a better mutual acquaintance'.</p> <p>They have to be included in a TPE course, that's all for those who didn't speak or write French well, by questioning them I was able to see that they had the expected reasoning, they got involved and took advantage of the session like the others.</p> <p>He's got as well with the hearing-impaired person. For the motor disability, the patient who was moving very badly did not play the scenario but was very active in the rest of the study. 2/3</p>	<p>'Excessive outside noise'. 2/3</p> <p>'The sound wasn't optimum'.</p> <p>'Sounds promising, superior to the paper-and-pencil methods'.</p>	<p>'The organisation, the professionalism of the facilitators'.</p> <p>The objectives of some patients were not those targeted. Fear of 'doing wrong, of being clumsy, of not being responsive enough to encourage patients to express themselves'.</p> <p>'Maybe go over some of the wording in our debriefing questions. 1/3</p> <p>'Better detailing and guidance for synthesis - even more patient-friendly'. 2/3</p> <p>It was very rewarding to use a new method, to share this TPE experience with other professionals. I've grown in skill and confidence. This tool can be very enriching for patients, it could be used during the stay with specific objectives. This allowed them to refine, confront and learn. I appropriated the method once the apprehension passed that made me mature, has been more experience to continue with other tools. It made me aware of what I still had to work on, such as managing the group, how to refocus them, how to bring them back with benevolence. 3/3</p> <p>The teamwork was very rich. A complicity has appeared, there is a better mutual acquaintance.</p> <p>'One of the workshops has been more difficult: less listening. Some participants spoke without hearing what was being said, as in other methods'</p> <p>It is necessary for the patient to be included in a TPE group session, the number could influence the group dynamics up to eight to ten max but beyond that it is difficult.</p> <p>'Aiming for goals that concern them'.</p> <p>They are attentive in action, they take notes, note the difficulties. They are involved in analysis and the search for improvement. They confront each other in their practices. It's a fun method that appeals to all the senses: visual, auditory, kinesthetic. This method allows each person to express themselves, their daily life, they were able to communicate, exchange, share and they need it. It is more concrete than other approaches, the training was very constructive, with the multi-professional team, the different experiences, the very rich sharing, participating in a research is to grow, to learn, to question oneself, to advance.</p> <p>The development of coping skills (not feeling alone, gaining self-confidence, managing stress, talking about one's illness) is a complete overview of the issue (hypoglycaemia in this case) and is used in all its dimensions.</p> <p>It's concrete, speaking, explicit, it's lived for for them, they recognised themselves in the situation'.</p> <p>3/3 S-TPE is relevant with patients.</p>	<p>The duration is OK</p> <p>'Thus staying within the time of a classic 2-hour session'.</p>
<p>'What do you see as the limitations of using TPE simulation to enable patients to learn how to manage their disease on a daily basis?'</p> <p>'What do you see as the benefits of using TPE simulation to help patients learn how to manage their disease on a daily basis?'</p>	<p>Perfection in group facilitation. Awareness that I need other tools to manage a group.</p>	<p>Improvement of the technical part, especially the sound part.</p>	<p>Better target patients vs goals. Reducing goals.</p>	

S-TPE, Simulation for Therapeutic Patient Education.

with diabetes.<sup>28</sup> Like another small pilot study,<sup>29</sup> we could not show that S-TPE improved self-efficacy in patients.

In contrast to the heterogeneous approaches French health authorities take towards TPE in type 1 and type 2 diabetes, we took a standardised approach to evaluating S-TPE, building on a consensus conference that we recently conducted and published.<sup>22</sup> These recommendations were to involve ‘expert patients’ (patients recognised for their advanced understanding of the condition) in constructing the scenarios we used.

Our pilot study demonstrated the acceptability and feasibility of S-TPE for adult patients with diabetes and provided preliminary data that we will use to design and conduct a large randomised controlled trial to evaluate efficacy of S-TPE in diabetes.

Educators said that they ‘increased skill and confidence’, that ‘this tool could be used during the hospital stay with specific objectives’ and that ‘the pluridisciplinary team-work in TPE was richer’, but studies that include more educators are needed to determine if our positive results are consistent and generalisable. These studies should determine the optimal duration and number of training sessions for educators. If S-TPE works for patients with diabetes, it should be possible to extend the programme to provide S-TPE to patients with other chronic conditions. Expert patients should be systematically involved at an early stage when designing interventions to improve TPE programmes and specifically S-TPE.

This pilot study opens a path to testing the intervention in a larger, more representative population of patients and educators. If the results of our future efficacy trial of S-TPE in patients with diabetes are positive, this method may improve the management of diabetes by patients and educators, by unlocking self-skills previously not accessible, and transform TPE as a patient-centred approach. It will also open the possibility to transpose this method in other chronic diseases.

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**Contributors** Each author contributed to the research. CP initiated the project and followed all the steps, ML guided the analysis of the results and the writing of the article. CM and RG followed up on the methodology of the TPE and the recommendations. ND, SR, A-MH, AD and DC made the implementation of the project possible and MB supervised the research methodology and the writing of the article. CP is the guarantor of this study.

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