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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 ±SD 63±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±4.5 to 32.7±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.

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.[6] TPE reduces hospital stays and costs,[7 8] but there are not enough trained educators, especially in remote areas.[9] Most TPE programmes only offer instruction but neglect skills necessary for everyday life.[10–12] Some self-care skills may be difficult to acquire during TPE, including managing uncontrolled and severe hypoglycaemia.[13]

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*[10] 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

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.[1 2] TPE has met the needs of patients with diabetes,[3] asthma[4] and heart failure.[5] Patient benefits include greater

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.[14] Simulation improves self-efficacy in parents caring for children with diabetes and children leaving neonatal care.[15 16] Simulation develops skills in professionals but is not yet integrated into TPE.[14] Whether simulation would extend the benefits of TPE is a matter of debate. Coleman[17] advocated its use because it was successful in training programmes for health professionals, but Lefèvre *et al*[18] 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),[19] 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).[20] 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,[21] and on criteria for measuring the quality of therapeutic education,[7] 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.[22] 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.[23]

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.[24]
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.[22] 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 χ^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 **descriptive phase**, patients can describe their impressions and then express emotions and feelings. In the **analysis phase**, 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.[25] 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).[26]

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[27] 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-Y 2 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 (3.3; 27–40)	35.6 (3.0; 28–40)	0.29
Men‡				35.5 (6.9; 22–49)	34.2 (7.8; 21–46)	32.1 (5.2; 22–45)	0.17			
Women‡				36.1 (4.8; 29–45)	35.1 (4.5; 29–43)	32.7 (5.5; 27–44)	0.04			

*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)		
'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'		
Limitations on the use of S-TPE			
Positive consideration (21/23)	Improvement relating to duration (1/23)	Improvement in group expression (1/23)	
'None', 'nothing'	'A little long, no more than 2 hours'	'Too many people, not easy to express yourself in front of others'	
Benefits of using S-TPE			
Relationship skills (7/23)	Pedagogical qualities (15/23)	Effects on daily life (8/23)	
'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'	
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)
'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'

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 ($51.9\pm4.9/60$).

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 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
Right after the S-TPE 'Describe in a few words what you've appreciated in this TPE session'.	'Cooperation and collaboration with all stakeholders. 3/3 The good mood of the group the participation' 3/3 'Patients' attention, yet relaxed; their participation'.	'Excessive outside noise'. 2/3	'The organisation, the professionalism of the facilitators'.	The duration is OK
'Describe in a few words what may have bothered you in the TPE session'.	'A lot of stress and finally it has a good time'.		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'.	
'How could this TPE session be improved?'			'Maybe go over some of the wording in our debriefing questions. 1/3 'Better detailing and guidance for synthesis - even more patient-friendly'. 2/3	
At a distance from the session: 'What would you like to say about the sessions that used the simulation today?'	'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'.	'The sound wasn't optimum'.	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 The teamwork was very rich. A complicity has appeared, there is a better mutual acquaintance.	
'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?'	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. 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		'One of the workshops has been more difficult: less listening. Some participants spoke without hearing what was being said, as in other methods' It is necessary for the patient to be included in a TPE group session, the number could influence the group dynamics up to eight was perfect, up to 10 max but beyond that it is difficult. 'Aiming for goals that concern them'.	
'What do you see as the benefits of using TPE simulation to help patients learn how to manage their disease on a daily basis?'		'Sounds promising, superior to the paper-and-pencil methods'.	'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, kinaesthetic. 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.' 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. It's concrete, speaking, explicit, it's lived for them, they recognised themselves in the situation'. 3/3 S-TPE is relevant with patients.	
''What improvements would you suggest for the use of simulation in S-TPE?'	Perfection in group facilitation. Awareness that I need other tools to manage a group.	Improvement of the technical part, especially the sound part.	'The synthesis time could be more relevant, for example: ask them what they would do in the event of a future hypoglycaemia, precisely, and have them say what the consequences would be'. Better target patients vs goals. Reducing goals.	'Thus staying within the time of a classic 2-hour session'.

S-TPE, Simulation for Therapeutic Patient Education.

with diabetes.[28] Like another small pilot study,[29] 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.[22] 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 teamwork 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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Appendix 1

Grille d'évaluation du sentiment d'auto-efficacité de la S-ETP pour les patients avant et après V4.

French Adaptation of the General Self-Efficacy Scale

Michelle Dumont, Ralf Schwarzer & Matthias Jerusalem, Berlin, Germany, 2000

Auto-efficacité adaptée à l'utilisation du Free Style Libre

Code patient :…………………………………Date et heure de remplissage:………………………

Lisez attentivement chaque phrase et encerclez le chiffre qui vous décrit le mieux.

1. Je peux toujours arriver à adapter mon traitement d'insuline aux courbes du Free Style Libre.

pas du tout d'accord	Très peu d'accord	Moyen-nement d'accord	Totale-ment d'accord
1	2	3	4

2. Quelles que soient les circonstances je peux adapter mon traitement à l'insuline.

pas du tout d'accord	Un peu d'accord	Moyen-nement d'accord	Totale-ment d'accord i
1	2	3	4

3. C'est facile pour moi de maintenir mes glycémies dans les normes fixées grâce au Free Style Libre.

pas du tout d'accord	Un peu d'accord	Moyen-nement d'accord	Totale-ment d'accord i
1	2	3	4

4. J'ai confiance, je peux faire face efficacement aux événements inattendus et ajuster mon traitement d'insuline.

pas du tout d'accord	Un peu d'accord	Moyen-nement d'accord	Totale-ment d'accord i
1	2	3	4

5. Grâce à ma débrouillardise, je sais comment faire face aux situations imprévues.

pas du tout d'accord	Un peu d'accord	Moyen-nement d'accord	Totale-ment d'accord i
1	2	3	4

6. Je peux résoudre la plupart de mes problèmes glycémique si je m'investis suffisamment.

pas du tout d'accord	Un peu d'accord	Moyen-nement d'accord	Totale-ment d'accord
1	2	3	4

7. Je peux rester calme lorsque je suis confronté à des déséquilibres glycémiques car je peux me faire confiance pour faire face aux problèmes.

pas du tout d'accord	Un peu d'accord	Moyen-nement d'accord	Totale-ment d'accord
1	2	3	4

8. Lorsque je suis confronté à un déséquilibre glycémique, je peux maintenant trouver plusieurs solutions.

pas du tout d'accord	Un peu d'accord	Moyen-nement d'accord	Totale-ment d'accord i
1	2	3	4

9. Peu importe ce qui arrive dans la gestion de ma glycémie, je suis capable d'y faire face généralement.

2

pas du tout d'accord	Un peu d'accord	Moyen-nement d'accord	Totale-ment d'accord i
1	2	3	4

-

Appendix 2

Test auto-administré d'anxiété IASTA-Y1 (dans la vie quotidienne) à réaliser avant la S-ETP.

QUESTIONNAIRE D'ÉVALUATION PERSONNELLE IASTA (Forme Y-1)

Code patient :…………………………………Date de remplissage:………………………

 Genre : féminin ☐masculin☐

Ci-après figurent un certain nombre de déclarations que les personnes utilisent souvent pour se décrire. Lisez chacun des énoncés et cochez dans la case appropriée de droite ce qui convient le mieux à la façon dont vous vous sentez **en général.**

Il n'existe ni bonnes ni mauvaises réponses. Ne passez pas trop de temps sur chacun des points, mais donnez la réponse qui semble décrire le mieux ce que vous ressentez **généralement.**

Répondez à toutes les questions et ne cochez qu'une case (par un X) pour chacune d'entre elles.

A présent, répondez à la liste suivante par : Presque jamais, parfois, souvent, presque toujours.

1 Je me sens dans de bonnes dispositions	Presque jamais	Parfois	Souvent	Presque toujours
2 Je me sens nerveux et agité	Presque jamais	Parfois	Souvent	Presque toujours
3 Je suis content de moi	Presque jamais	Parfois	Souvent	Presque toujours
4 Je voudrais être aussi heureux que les autres semblent l'être	Presque jamais	Parfois	Souvent	Presque toujours
5 Je me sens un raté	Presque jamais	Parfois	Souvent	Presque toujours
6 Je me sens paisible	Presque jamais	Parfois	Souvent	Presque toujours
7 Je suis calme, détendu et de sang froid	Presque jamais	Parfois	Souvent	Presque toujours
8 J'ai l'impression que les difficultés se multiplient à un point tel que je ne peux les surmonter	Presque jamais	Parfois	Souvent	Presque toujours
9 Je m'inquiète trop à propos de choses qui n'en valent pas la peine	Presque jamais	Parfois	Souvent	Presque toujours
10 Je suis heureux	Presque jamais	Parfois	Souvent	Presque toujours
11 J'ai des pensées qui me tourmentent	Presque jamais	Parfois	Souvent	Presque toujours
12 Je manque de confiance en moi	Presque jamais	Parfois	Souvent	Presque toujours
13 je suis sûr de moi	Presque jamais	Parfois	Souvent	Presque toujours
14 Je prends facilement des décisions	Presque jamais	Parfois	Souvent	Presque toujours
15 Je ne me sens pas à la hauteur	Presque jamais	Parfois	Souvent	Presque toujours

16 Je suis content	Presque jamais	Parfois	Souvent	Presque toujours
17 Des pensées sans importance me trottent dans la tête et me tracassent	Presque jamais	Parfois	Souvent	Presque toujours
18 Je ressens les contretemps si fortement que je ne peux les chasser de mon esprit	Presque jamais	Parfois	Souvent	Presque toujours
19 Je suis quelqu'un de calme	Presque jamais	Parfois	Souvent	Presque toujours
20 Je suis tendu ou agité dès que je réfléchis à mes soucis et problèmes actuels	Presque jamais	Parfois	Souvent	Presque toujours

Compter 1 point pour la réponse Presque jamais, 2 points pour la réponse Parfois, 3 points pour la réponse Souvent et 4 point pour la réponse Presque toujours pour les questions 2,4,5,8,9,11,12,15,17,18,20.

Pour les questions 1,3,6,7,10,13,14,16,19: la cotation est inversée c'est-à-dire qu'il faut compter 4 points pour Presque jamais, 3 points pour Parfois, 2 points pour Souvent et 1 point pour Presque toujours.

Puis faites le total de vos points…
Chez les femmes la moyenne est de 47.

Chez les hommes la moyenne est de 39

Si vous êtes au-dessus de cette moyenne, vous avez une personnalité anxieuse. Au plus votre score est élevé au plus vous présentez une anxiété importante.

Chez les hommes, si vous dépassez le score de 51, vous êtes très anxieux et ceci interfère sur votre qualité de vie.

Chez les femmes, si vous dépassez le score de 61, vous êtes très anxieuse et ceci interfère sur votre qualité de vie.

Test auto-administré d'anxiété IASTA-Y2 (situationnelle) à réaliser avant et après la S-ETP.

QUESTIONNAIRE D'ÉVALUATION PERSONNELLE IASTA (Forme Y-2)

Code patient N° :…………………………………Date et heure de remplissage:………………………

Genre : féminin ☐ masculin ☐

Dans quelques instants, vous allez vivre une situation complexe à gérer en lien avec votre Free Style Libre®.

Ci-après figure un certain nombre de déclarations que les personnes utilisent pour se décrire.

Lisez chacun des énoncés et cochez dans la case appropriée de droite (par un X) ce qui convient le mieux à la façon dont vous vous sentez maintenant, juste avant cette situation. Il n'existe ni bonnes ni mauvaises réponses. Ne passez pas trop de temps sur chacun des points, mais donnez la réponse qui semble décrire le mieux ce que vous ressentez à cet instant.

Répondez à toutes les questions et ne cochez qu'une case pour chacune d'entre elles.

A présent, répondez à la liste suivante par : Pas du tout, un peu, modérément, beaucoup

1 Je me sens calme	Pas du tout	Un peu	Modérément	Beaucoup
2 Je me sens sûr de moi	Pas du tout	Un peu	Modérément	Beaucoup
3 Je suis tendu	Pas du tout	Un peu	Modérément	Beaucoup
4 Je me sens contraint	Pas du tout	Un peu	Modérément	Beaucoup
5 Je me sens à mon aise	Pas du tout	Un peu	Modérément	Beaucoup
6 Je me sens bouleversé	Pas du tout	Un peu	Modérément	Beaucoup
7 Je m'inquiète à l'idée de malheurs possibles	Pas du tout	Un peu	Modérément	Beaucoup
8 Je me sens satisfait	Pas du tout	Un peu		

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			Modérément	Beaucoup
9 J'ai peur	Pas du tout	Un peu	Modérément	Beaucoup
10 Je me sens bien	Pas du tout	Un peu	Modérément	Beaucoup
11 J'ai confiance en moi	Pas du tout	Un peu	Modérément	Beaucoup
12 Je me sens nerveux	Pas du tout	Un peu	Modérément	Beaucoup
13 Je suis agité	Pas du tout	Un peu	Modérément	Beaucoup
14 Je me sens indécis	Pas du tout	Un peu	Modérément	Beaucoup
15 Je suis détendu	Pas du tout	Un peu	Modérément	Beaucoup
16 Je suis content	Pas du tout	Un peu	Modérément	Beaucoup
17 Je suis inquiet	Pas du tout	Un peu	Modérément	Beaucoup

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18 Je me sens troublé	Pas du tout	Un peu	Modérément	Beaucoup
19 Je me sens stable	Pas du tout	Un peu	Modérément	Beaucoup
20 Je me sens dans de bonnes dispositions	Pas du tout	Un peu	Modérément	Beaucoup

Pour se faire il vous suffit de :

Compter 1 point pour la réponse 'Pas du tout', 2 points pour la réponse 'Un peu', 3 points pour la réponse 'Modérément' et 4 point pour la réponse 'Beaucoup' pour les questions 3, 4, 6, 7, 9, 12, 13, 14, 17, 18. > Pour les questions 1, 2, 5, 8, 10, 11, 15, 16, 19, 20, la cotation est inversée c'est-à-dire qu'il faut compter 4 points pour 'Pas du tout', 3 points pour 'Un peu', 2 points pour 'Modérément et 1 point pour 'Beaucoup'.

Puis faites le total de vos points...

Chez les femmes la moyenne est de 42. > Chez les hommes la moyenne est de 37.

Si vous êtes au-dessus de cette moyenne, la situation génère une anxiété importante. Au plus votre score est élevé au plus cette situation est vécue de façon anxiogène.

Chez les hommes, si vous dépassez le score de 48, votre anxiété interfère sur les performances. Chez les femmes, si vous dépassez le score de 55, votre anxiété interfère sur les performances.

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Appendix 3

Questionnaire auto-administré de perception d'utilité des patients à la fin de la séance de simulation.

Code patient N° :…………………………………Date de remplissage:………………………

Entourez le chiffre correspondant à votre opinion de 1 : fortement en désaccord à 5 : tout à fait d'accord.

1. Cette séance d'ETP m'a permis d'approfondir la façon d'utiliser mon Free Style Libre® pour réguler mes glycémies dans mon quotidien.

1	2	3	4	5
Fortement en désaccord	En désaccord	Neutre	D'accord	Tout à fait d'accord

2. Cette séance d'ETP m'a permis de réfléchir sur mes actions avec le Free Style Libre®.

1	2	3	4	5
Fortement en désaccord	En désaccord	Neutre	D'accord	Tout à fait d'accord

3. Cette séance d'ETP a augmenté ma motivation à réguler ma glycémie.

1	2	3	4	5
Fortement en désaccord	En désaccord	Neutre	D'accord	Tout à fait d'accord

4. Cette séance d'ETP a augmenté ma confiance en ma capacité à gérer mes glycémies par le Free Style Libre®.

1	2	3	4	5
Fortement en désaccord	En désaccord	Neutre	D'accord	Tout à fait d'accord

5. Cette séance d'ETP a été utile, pour pouvoir utiliser le Free Style Libre et adapter mon traitement par insuline.

1	2	3	4	5
Fortement en désaccord	En désaccord	Neutre	D'accord	Tout à fait d'accord

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Appendix 4

Questionnaire auto-administré du niveau d'utilité identification des facilités et limites organisationnelles, humaines et matérielles, pour les soignants à la fin de chaque séquence de simulation.

Soignant No:_____ Date:_____

Entourez le chiffre correspondant à votre opinion de 1 : fortement en désaccord à 5 : tout à fait d'accord.

1. Le lieu de cette séance d'ETP m'a convenu.

1	2	3	4	5
Fortement en désaccord	En désaccord	Neutre	D'accord	Tout à fait d'accord

2. La durée de cette séance d'ETP m'a convenu.

1	2	3	4	5
Fortement en désaccord	En désaccord	Neutre	D'accord	Tout à fait d'accord

3. La qualité des échanges m'a convenu.

1	2	3	4	5
Fortement en désaccord	En désaccord	Neutre	D'accord	Tout à fait d'accord

4. Le matériel et l'équipement utilisés dans cette séance d'ETP m'ont convenu.

1	2	3	4	5
Fortement en désaccord	En désaccord	Neutre	D'accord	Tout à fait d'accord

5. Cette séance de simulation en ETP va me permettre de progresser professionnellement.

1	2	3	4	5

| Fortement en désaccord | En désaccord | Neutre | D'accord | Tout à fait d'accord |

6. Cette séance d'ETP est utile aux patients.

| 1 | 2 | 3 | 4 | 5 |

| Fortement en désaccord | En désaccord | Neutre | D'accord | Tout à fait d'accord |

7. Je recommande cette séance d'ETP à d'autres patients.

| 1 | 2 | 3 | 4 | 5 |

| Fortement en désaccord | En désaccord | Neutre | D'accord | Tout à fait d'accord |

8. Je suis à l'aise avec la méthode de simulation utilisée dans cette séance d'ETP.

| 1 | 2 | 3 | 4 | 5 |

| Fortement en désaccord | En désaccord | Neutre | D'accord | Tout à fait d'accord |

Appendix 5

Questionnaire auto-administré de satisfaction des patients à la fin de la séance de simulation V4.

Code patient N° :…………………………….Date de remplissage:……………………….

Entourez le chiffre correspondant à votre opinion de 1 : fortement en désaccord à 5 : tout à fait d'accord.

1. Cette séance d'ETP m'a permis d'atteindre les objectifs fixés.

1	2	3	4	5
Fortement en désaccord	En désaccord	Neutre	D'accord	Tout à fait d'accord

2. Cette séance d'ETP a répondu à mes attentes.

1	2	3	4	5
Fortement en désaccord	En désaccord	Neutre	D'accord	Tout à fait d'accord

3. Cette séance d'ETP va me permettre de progresser.

1	2	3	4	5
Fortement en désaccord	En désaccord	Neutre	D'accord	Tout à fait d'accord

4. Cette séance d'ETP a permis de répondre à mon questionnement.

1	2	3	4	5
Fortement en désaccord	En désaccord	Neutre	D'accord	Tout à fait d'accord

5. La méthode utilisée dans cette séance d'ETP m'a convenu.

1	2	3	4	5
Fortement en désaccord	En désaccord	Neutre	D'accord	Tout à fait d'accord

6. Le lieu de cette séance d'ETP m'a convenu.

1	2	3	4	5
Fortement en désaccord	En désaccord	Neutre	D'accord	Tout à fait d'accord

7. La durée de cette séance d'ETP m'a convenu.

1	2	3	4	5
Fortement en désaccord	En désaccord	Neutre	D'accord	Tout à fait d'accord

8. La qualité des échanges entre participants m'a convenu.

1	2	3	4	5
Fortement en désaccord	En désaccord	Neutre	D'accord	Tout à fait d'accord

9. La qualité des échanges avec les professionnels m'a convenu.

1	2	3	4	5
Fortement en désaccord	En désaccord	Neutre	D'accord	Tout à fait d'accord

10. Le matériel et l'équipement utilisés dans cette séance d'ETP m'ont convenu.

1	2	3	4	5
Fortement en désaccord	En désaccord	Neutre	D'accord	Tout à fait d'accord

11. J'ai bien vécu cette séance d'ETP.

1	2	3	4	5
Fortement en désaccord	En désaccord	Neutre	D'accord	Tout à fait d'accord

12. Je recommande cette séance d'ETP à un autre patient.

1	2	3	4	5
Fortement en désaccord	En désaccord	Neutre	D'accord	Tout à fait d'accord

<u>Appendix 6</u>

Grille d'entretien d'évaluation évaluant le niveau de perception d'utilité de la Simulation en ETP pour les patients, écrite en post S-ETP et par téléphone à 15-30 jour.

Code patient :…………………………………Date de remplissage:………………………

1. Concernant la séance ayant utilisée la simulation (rappeler la situation travaillée), qu'auriez-vous envie d'en dire aujourd'hui ?

………………………………………………………………………………………………

Reprendre et préciser les éléments du premier questionnaire avec une utilité faible.

………………………………………………………………………………………………

2. Quels sont, pour vous, les limites de l'utilisation de la simulation en ETP pour permettre aux patients d'apprendre à gérer leur maladie au quotidien ?

………………………………………………………………………………………………

3. Quels sont, pour vous, les avantages à l'utilisation de la simulation en ETP pour permettre aux patients d'apprendre à gérer leur maladie au quotidien ?

………………………………………………………………………………………………

4. Quelles améliorations proposeriez-vous pour l'utilisation de la simulation en ETP?

………………………………………………………………………………………………

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Appendix 7

Grille d'entretien afin d'approfondir avec les soignants les facilités et limites organisationnelles, humaines, matérielles, temporelles de l'utilisation de la simulation dans le cadre de l'ETP, à la fin de de la S-ETP par écrit et 15 à 30 jours après la séance par téléphone.

Soignant N° :_____ Date:_____

1. Concernant les séances ayant utilisée la simulation (rappeler la situation travaillée), qu'auriez-vous envie d'en dire aujourd'hui ?

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2. Quels sont, pour vous, les limites de l'utilisation de la simulation en ETP pour permettre aux patients d'apprendre à gérer leur maladie au quotidien ?

…………………………………………………………………………………………

3. Quels sont, pour vous, les avantages de l'utilisation de la simulation en ETP pour permettre aux patients d'apprendre à gérer leur maladie au quotidien ?

…………………………………………………………………………………………

4. Quelles améliorations proposeriez-vous pour l'utilisation de la simulation en ETP?

…………………………………………………………………………………………

Supplementary Figure 1 : Design of S-TPE intervention