Efficacy of targeted education in reducing topical steroid phobia: A randomized clinical trial

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Background: Fear of adverse effects of corticosteroids is common in dermatology and results in medication nonadherence.

Objective: To study the efficacy of targeted education in reducing topical steroid phobia.

Methods: In this double-blinded, randomized controlled trial, participants in the intervention arm were presented with an educational video and patient information leaflet targeting common misconceptions of topical corticosteroids. Steroid phobia was assessed with the topical corticosteroid phobia (TOPICOP) scale, medication adherence with the Elaboration d'un outil d'evaluation de l'observance des traitements medicamenteux (ECOB) score, and quality of life with the Dermatology Life Quality Index (DLQI).

Results: The study randomized 275 patients. The mean TOPICOP score in the intervention arm decreased (improved) from 41.9 (SD, 17.4) to 37.1 (SD, 20.0) and to 33.8 (SD, 19.0) at 1 month and 3 months, respectively, with the reduction arising from the knowledge domain but not the fears and behaviors domain. This remained statistically significant after adjusting for demographic confounding with an expected reduction of 4.22 points (P = .031). After accounting for demographic factors, there was no statistical difference in medication adherence and quality of life. Limitations include the exclusion of non—English-speaking patients.

Conclusion: Targeted education at a single time point improved the TOPICOP score primarily in the knowledge domain but not in the fear domain. (J Am Acad Dermatol 2020;83:1681-7.)

Key words: atopic dermatitis; health services research; patient education; randomized controlled trial; steroid phobia; topical corticosteroids; topical steroid concern.

Topical corticosteroids (TCSs) are used commonly in dermatology for their anti-inflammatory properties. There is large evidence that TCSs are safe when used appropriately[1]; however, the fear of adverse effects of TCSs—steroid phobia—is common, with a prevalence of 21.0% to 83.7%.[2,3] Steroid phobia can result in nonadherence,[4] which may lead to poorly controlled disease and increased flares.

A prior survey of 181 patients in our center[5] found that 40% of patients expressed fear of applying too much TCS cream and that 50% needed reassurance about its use. Fear of adverse effects was common, with almost half of participants agreeing that TCSs

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pass into the bloodstream and affect their future health. Of participants with fewer than 2 weeks of TCS use, 16% reported experiencing adverse effects, potentially representing some degree of misunderstanding about steroid side effects. Results from this previous study were incorporated into the Health Belief Model[6] as an explanatory theory to guide the development of our intervention to target behavioral change.

The objective of this trial was to study the efficacy of targeted education in reducing steroid phobia and whether a reduction in steroid phobia would lead to improved medication adherence and quality of life. We also planned to test the efficacy of involvement in moderated social forum groups in reducing steroid phobia.

We postulated that nonadherence to TCSs in our population arose predominantly from a distorted perception of benefits vs harms and the lack of confidence in safely using TCSs. We hypothesized that the introduction of educational materials targeting common misconceptions and teaching safe use of TCSs would reduce steroid phobia and improve adherence, thereby resulting in an improved quality of life.

CAPSULE SUMMARY

- Topical steroid phobia is prevalent in dermatology and affects adherence to treatment.
- Education targeted at common misconceptions improved understanding of but not adherence to topical steroids.

METHODS

Study design

This was a prospective, patient- and physician-blinded, randomized, controlled trial conducted between October 2018 and May 2019 at the Division of Dermatology, National University Hospital, Singapore. The National Healthcare Group Domain Specific Review Board approved the study (DSRB Ref. No. 2018/00481). The study protocol was prospectively registered with ClinicalTrials.gov (Identifier: NCT03658252) and available in Supplemental Material 1 (available via Mendeley at https://doi.org/10.17632/zjd58fyk5b.1). Written informed consent was obtained from all patients. This study was funded by a health services research grant from the National University Health System.

Participants and eligibility

Consecutive patients in the dermatology outpatient clinics were screened for eligibility. Inclusion criteria were age older than 21 years, having been prescribed and expected to be on a TCS for the next 3 months for a dermatologic condition (without restriction on the dermatologic diagnosis), being able to read and understand English, and having a telephone number and email address. Exclusion criteria included participants on a short-term TCS (<3 months) for an acute dermatologic condition and inadequate command of English. If patients attended in a group (eg, siblings consulting the doctor), only 1 member was recruited to prevent cross-contamination of the intervention.

Randomization and blinding

Participants were randomized to the control or intervention arm in a 1:1 ratio using computerized block randomization (block size of 4). Intervention assignments were allocated by the study coordinator. Participants and clinicians were blinded to the assignments. To preserve the blinding, details of the educational intervention and specific intent of the trial were not disclosed to participants.

Intervention and control

Educational materials for the intervention arm were designed based on our understanding of the factors influencing steroid phobia, set in the theoretic framework of the Health Belief Model.[6] The constructs targeted were perceived severity, perceived benefits, perceived barriers, and self-efficacy (Fig 1). The intervention aimed to reframe the benefits of TCSs with potential adverse effects, motivate patients by relating adherence to what patients value—an improved skin condition, and enhance the capability of patients to self-manage.

The primary intervention consisted of a 2.5-minute video (Supplemental Material 2) designed to dispel common misconceptions. The video featured an elderly patient and her grandson, a medical student. Through casual conversations, steroid adverse effects, fears, and misconceptions were discussed in a relatable and nonconfrontational manner. There was active modeling of the use of the TCS with the fingertip unit to encourage self-efficacy. Nonforceful language, having laypeople deliver the message, and incorporating discussions on nonsteroidal alternatives served to avoid triggering psychologic reactance.[7]

The primary intervention also included a patient information leaflet on TCS (Supplemental Material 3) to reinforce information from the video in a factual

Abbreviations used:

CI:	confidence interval
DLQI:	Dermatology Life Quality Index
ECOB:	Elaboration d'un outil d'evaluation de l'observance des traitements medicamenteux
TCS:	topical corticosteroid
TOPICOP:	topical corticosteroid phobia

and straightforward manner. The Flesch Reading Ease score was 71.2 for the educational materials, corresponding to a Flesch-Kincaid grade level of 6.3 (classified as fairly easy to read).[8]

Delivery of the intervention was done discretely to prevent cross-contamination of the intervention. For instance, participants viewed the video on a tablet with earphones.

As a secondary intervention, participants in the intervention arm were encouraged to visit an online-moderated social network forum through an URL link sent to their email after completion of the questionnaire at 1 month.

Participants in the intervention and control arm received standard medical care by their dermatologist. The research assistant refrained from providing any counseling or delivery of information to participants.

Outcomes and measurements

Self-reported data on demographics, disease characteristics, confounders, such as perceived severity of skin condition and tolerance of itch, and measures of primary and secondary outcomes were collected before randomization.

The prespecified primary outcome measure was the change in degree of steroid phobia, measured using the topical corticosteroid phobia (TOPICOP) scale.[9,10] Secondary outcome measures were quality of life using the Dermatology Life Quality Index (DLQI)[11] and topical steroid adherence scores using the Elaboration d'un outil d'evaluation de l'observance des traitements medicamenteux (ECOB) score.[12,13]

The TOPICOP scale is a validated score to standardize the quantification of TCS phobia. It consists of 12 items assessing 3 domains of TCS phobia: knowledge and beliefs, fears, and behavior. The 10-question DLQI score is a widely used dermatology-specific quality of life instrument. The ECOB is a score composed of 4 questions to assess compliance to acne treatment. Given the scarcity of

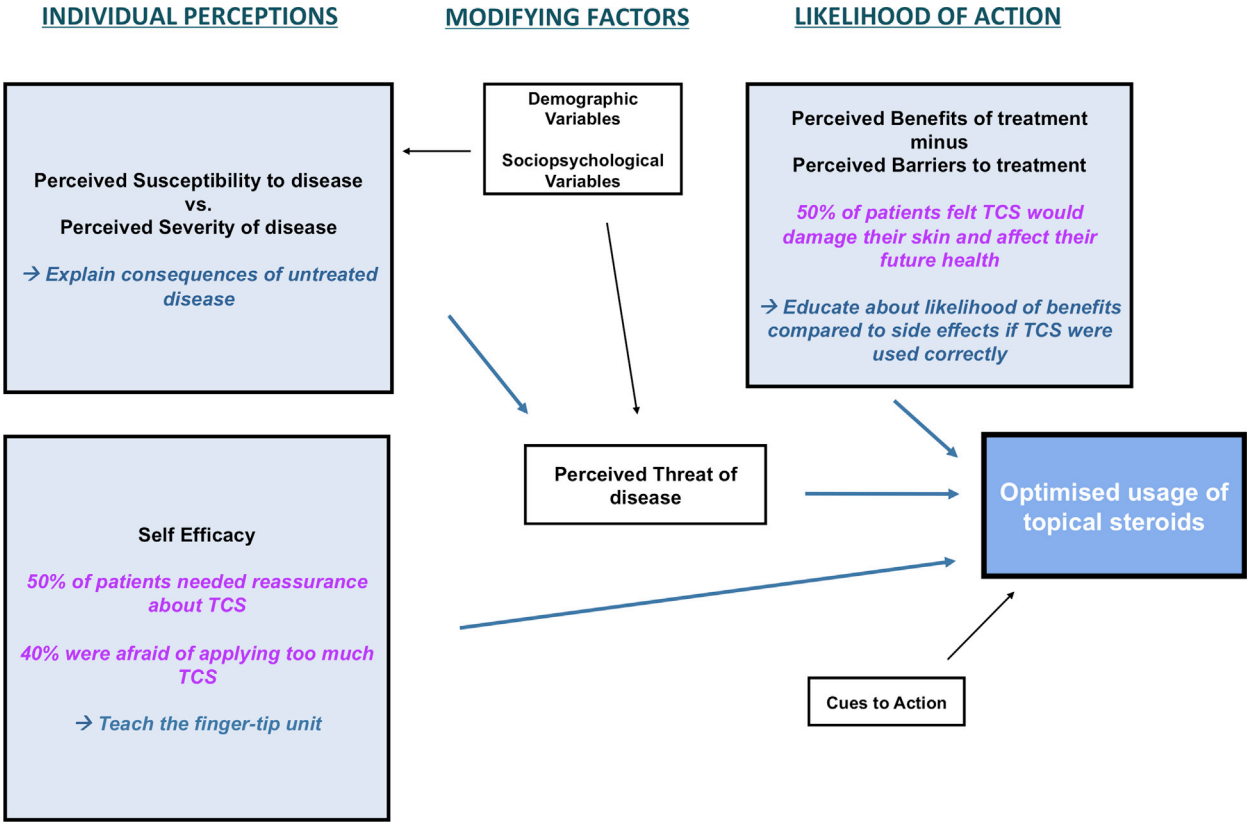

Fig 1. Health belief model in the context of steroid phobia. *TCS*, Topical corticosteroid.

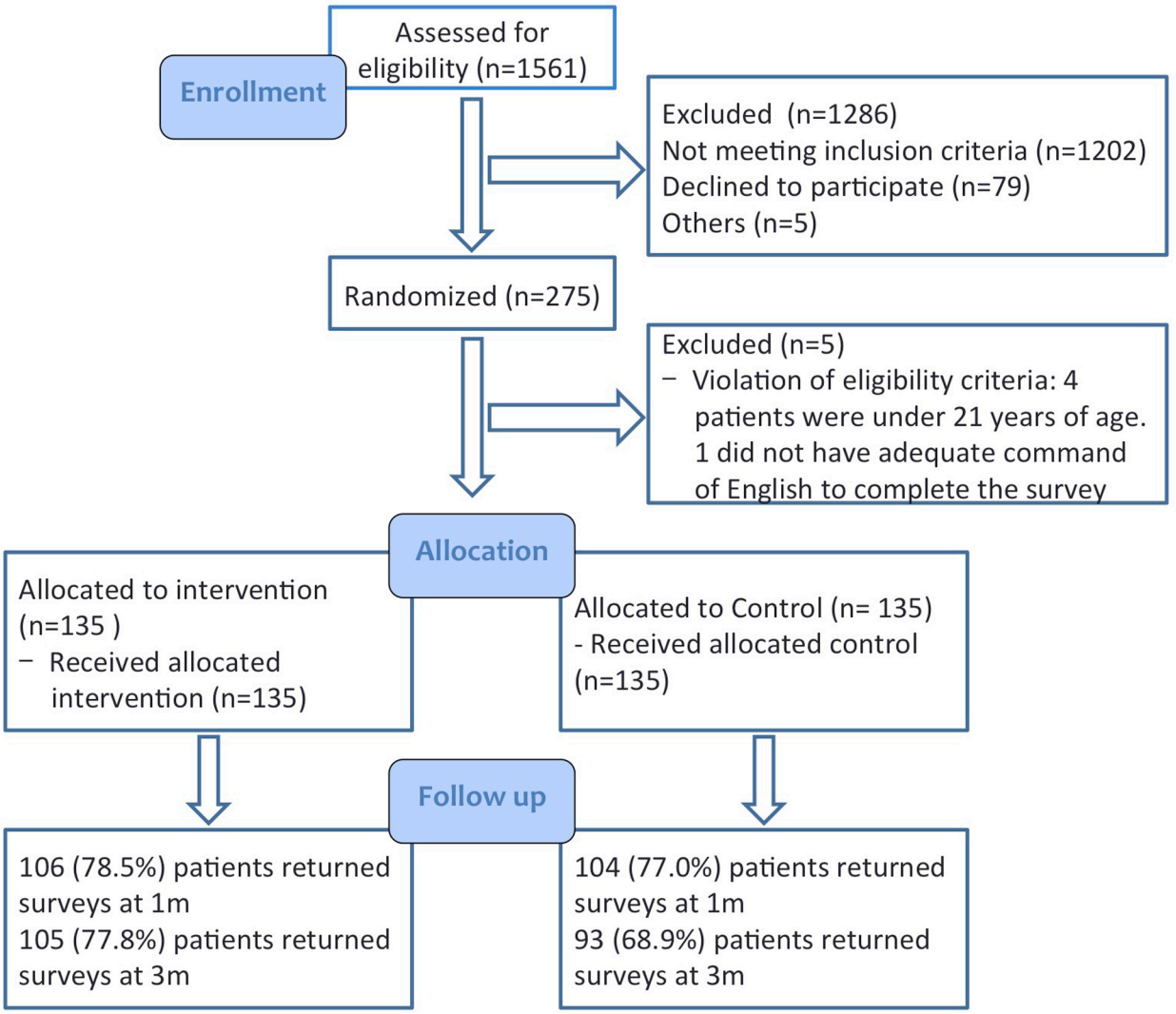

Fig 2. Consolidated Standards of Reporting Trials flow diagram.

scores for topical therapy adherence, the ECOB score was chosen, acknowledging the limitation that this was not its intended context of use. Required permissions for the above tools were obtained.

Follow-up survey questionnaires were emailed to all participants at 1 month and 3 months. A reminder email and telephone call was made if participants failed to return the questionnaires. Participants were compensated with a cash voucher after completion of both questionnaires.

Sample size calculation

Assuming that prospective participants of the present study would have a mean (SD) baseline TOPICOP score (44 [17.6]) similar to our previously surveyed sample,[5] a sample size of 216 would give an 80% power (α = 0.05) to detect a hypothesized 15% reduction in the TOPICOP score. To account for an expected attrition rate of 20%, we decided to recruit 270 patients (135 in each arm).

Statistical methods/data analysis

Participants were analyzed according to their randomized group using intention-to-treat analysis. Continuous variables are summarized using mean (SD), and categorical variables are presented as proportions and were tested for significant differences at baseline between the intervention and control arms.

We estimated the effect of the intervention using a repeated-measures mixed-effects model. The model included the intervention arm and time as fixed-effect factors, using an unstructured covariance type. Demographic confounders adjusted for included age, sex, race, and highest

Table I. Baseline characteristics of participants

Variable	Intervention arm (n = 135)	Control arm (n = 135)
Age, mean (SD), y	45 (16)	47 (16)
Male sex, No. (%)	75 (56)	69 (51)
Race/ethnicity, No. (%)		
Chinese	91 (67)	97 (72)
Malay	21 (16)	17 (13)
Indian	12 (9)	13 (10)
White	3 (2)	3 (2)
Others	8 (6)	5 (4)
Highest education, No. (%)		
Primary	3 (2)	3 (2)
Secondary	30 (22)	29 (21)
Junior college/ Polytechnic/ITE	48 (36)	46 (34)
Undergraduate degree	39 (29)	39 (29)
Postgraduate degree	14 (10)	17 (13)
Treatment characteristics, No. (%)		
Prescription of oral steroids	8 (6)	12 (9)
Prescription of systemic steroid-sparing immunosuppressant	23 (17)	28 (21)
Perceived tolerance to skin symptoms, No. (%)		
Lowest tolerance	17 (13)	18 (13)
Low tolerance	52 (39)	55 (41)
Moderate tolerance	45 (33)	47 (35)
High tolerance	21 (16)	14 (10)
Perceived severity of skin condition, No. (%)		
Lowest severity	11 (8)	6 (4)
Low severity	55 (41)	49 (36)
Moderate severity	50 (37)	46 (34)
High severity	19 (14)	33 (24)
Baseline TOPICOP score, mean (SD)	42 (17)	42 (17)

ITE, Institute of Technical Education; *TOPICOP*, topical corticosteroid phobia.

education attained. A sensitivity analysis was performed, excluding those with a TOPICOP score of <20% to assess whether those with low steroid phobia skewed the results. Statistical analysis was conducted using R Open 3.5.2 software (Microsoft, Redmond, WA).

RESULTS

Between October 2018 and January 2019, we screened 1561 prospective participants, excluded 1286, and randomized 275 (Fig 2). After randomization, 5 patients—4 aged younger than 21 years and 1 who had insufficient command of English—were withdrawn due to violation of protocol. These patients were excluded from the study, leaving a final sample of 270 participants. There was no crossover between groups. All participants remained in their allocated study arm. No adverse events or complaints were encountered.

Baseline demographics, perceived severity of skin condition, tolerance of itch, and TOPICOP scores were similar in both arms (Table I).

At the 3-month follow-up, only 3 participants in the intervention arm reported using the suggested social forum, with use between once every 1 to 3 weeks to less than once a month. Hence, the differences were assumed to have effectively resulted from only the primary intervention.

At 1 month and 3 months, mean TOPICOP score in the intervention arm decreased from 41.9 (SD, 17.4) to 37.1 (SD, 20.0) and to 33.8 (SD, 19.0), respectively. In the control arm, the score increased from 41.6 (SD, 16.8) to 44.6 (SD, 17.1) at 1 month and to 44.4 (SD, 17.6) at 3 months. There was a significant difference in DLQI at 3 months, with participants in the intervention arm scoring an average of 3 points lower at 3 months, implying better quality of life. Adherence was comparable in both arms (Fig 3).

In the repeated-measures mixed-effects model, older and female patients reported higher levels of baseline TCS phobia with greater TOPICOP scores. Older patients, however, reported lower baseline DLQI scores (Table II).

The intervention remained significant in reducing the TOPICOP score after adjusting for demographic confounding (β: −4.22; 95% confidence interval [CI], −8.04 to −0.41; P = .031). There was a decrease in the knowledge subscore (β: −6.39; 95% CI, −10.57 to −2.22; P = .002), but not in the subscores for behavior (β: −2.77; 95% CI, −8.17 to 2.63; P = .31) or fears (β: −1.72; 95% CI, −6.50 to 3.06; P = .48). The intervention did not have a significant effect on DLQI and ECOB after accounting for demographic factors (Table II).

A sensitivity analysis that omitted participants with low TCS phobia at baseline (TOPICOP score <20%) demonstrated similar results, with the same associations in the variables. This shows that participants with low TCS phobia did not skew the results (Supplementary Material 4).

DISCUSSION

This study provides evidence that targeted education at a single time point reduces the TOPICOP score, with this predominantly arising from the knowledge domain. The lack of reduction in the fears and behaviors domain, however, highlights the inherent difficulties of behavioral interventions in translating improved knowledge into clinically

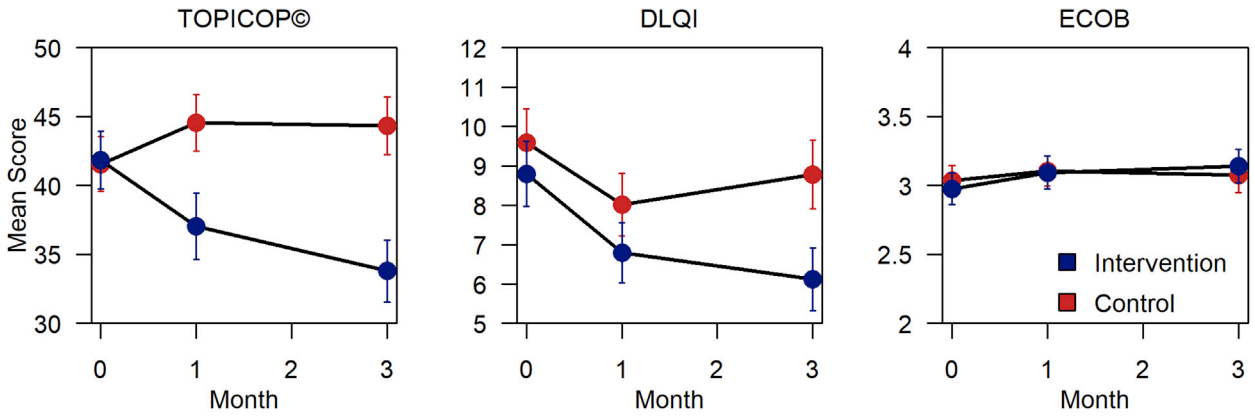

Fig 3. Line graphs show the change in topical corticosteroid phobia (*TOPICOP*), the Dermatology Life Quality Index (*DLQI*), and Elaboration d'un outil d'evaluation de l'observance des traitements medicamenteux (*ECOB*) scores over time in the intervention and control arm. The *range bars* show the 95% confidence interval.

Table II. Repeated-measures mixed-effect model results for TOPICOP, DLQI, and ECOB scores

Variable	TOPICOP*	*P* value	DLQI*	*P* value	ECOB*	*P* value
Intervention	−4.22 (−8.04 to −0.41)	.031†	−1.39 (−2.88 to 0.10)	.068	−0.03 (−0.23 to 0.17)	.793
Age	0.21 (0.08 to 0.34)	.002†	−0.07 (−0.12 to −0.02)	.012†	0.00 (−0.01 to 0.01)	.696
Female sex‡	4.62 (0.62 to 8.62)	.025†	1.18 (−0.38 to 2.74)	.139	−0.03 (−0.24 to 0.17)	.747
Race/ethnicity‡						
Malay	−0.92 (−6.78 to 4.94)	.758†	−0.16 (−2.44 to 2.12)	.892	0.31 (0 to 0.62)	.049
Indian	−1.03 (−8.18 to 6.12)	.778	0.44 (−2.34 to 3.23)	.755	−0.12 (−0.50 to 0.25)	.521
White	−9.08 (−22.25 to 4.09)	.178	−2.72 (−7.86 to 2.41)	.300	0.08 (−0.61 to 0.77)	.822
Others	−9.54 (−18.69 to −0.39)	.042†	−2.34 (−5.90 to 1.22)	.199	−0.04 (−0.52 to 0.44)	.870
Educational level‡						
Primary	1.13 (−13.11 to 15.36)	.877	−0.15 (−5.67 to 5.37)	.957	−0.24 (−1.00 to 0.53)	.545
Secondary	−3.44 (−9.11 to 2.23)	.235	−1.09 (−3.30 to 1.12)	.336	0.19 (−0.11 to 0.48)	.220
Undergraduate degree	−1.09 (−5.97 to 3.79)	.662	−2.07 (−3.97 to −0.17)	.034†	0.23 (−0.02 to 0.48)	.076
Postgraduate degree	3.25 (−3.47 to 9.97)	.344	−0.26 (−2.88 to 2.35)	.843	−0.02 (−0.37 to 0.34)	.926

DLQI, Dermatology Life Quality Index; *ECOB*, Elaboration d'un outil d'evaluation de l'observance des traitements medicamenteux; *TOPICOP*, topical corticosteroid phobia.

*Data are the β coefficients (95% confidence interval).

†Indicates statistical significance ($P < .05$).

‡Reference groups for sex, race/ethnicity, and educational status are male sex, Chinese, and Junior College/Polytechnic/Institute of Technical Education, respectively, the largest groups.

important outcomes.[14] The educational intervention, which improved patients' knowledge of TCS, may not have addressed a deep-seated, perhaps subconscious fear that prevents a change in behavior, and hence, did not translate to a clinically meaningful outcome of reduction in TCS phobia such as adherence to treatment or quality of life. Other factors, such as cost, inconvenience of treatment, disease characteristics, and symptom burden, potentially play a role in treatment adherence and its consequences.

The TOPICOP scale lacks cutoff values for the definition and degree of TCS phobia. This is partly due to the lack of existing diagnostic criteria for TCS phobia. In addition, although a high TOPICOP score represents high TCS phobia, a very low score reflects a lack of understanding about TCS safety. We described this and other limitations of the TOPICOP scale in a separate report and offered suggestions on how other authors may overcome these.[15] Studies to determine correlation between TCS phobia and measures such as adherence, disease severity, and quality of life will better characterize TCS phobia and facilitate the development of cutoff ranges. Furthermore, the ECOB might wrongly penalize an adherent patient tapering TCS. In addition, with only 4 questions and binary options, detecting differences between arms is challenging.

The development of validated tools for the specific measurement of TCS adherence is desired.

Benefits of our primary intervention include the low level of human resources and costs required to administer the video and patient information leaflet, making it inexpensive and feasible to implement on larger scales.

Factors such as the fear of patients or inability to articulate their concerns, limited consultation time, or failure of the physician to address their fears may result in persistence of TCS misconceptions. Although this does not replace the need for physicians to address TCS phobia, providing information through a different avenue can be synergistic and encourage retention of information, serving as a useful adjunctive tool.

Online forums and social support can be effective tools for adherence[16,17]; however, the internet is also a source of misinformation and misrepresentation of TCS.[5,18] Failure to consider local preferences, such as the low use of moderated online social forums in our country, may result in poor uptake of the intervention such as the low use of the recommended social forum in this study. A different prong of interventions is needed to curtail this misinformation about TCS on the internet. Another limitation of this study is that only English-speaking patients were recruited, excluding elderly patients who only speak their native non-English languages.

CONCLUSION

TCS phobia is prevalent and can be challenging to address in daily clinical practice. Use of adjunctive counseling materials that provide information in a relevant, relatable, and nonthreatening manner is an effective option in tackling misunderstandings about TCS adverse effects, but further studies are required to optimize and assess the effect of interventions in reducing fear of TCS use and improving clinically relevant outcomes such as treatment adherence and quality of life.

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