ORIGINAL RESEARCH

Use of high-fidelity simulation in advancing palliative care skills in nursing students: A convergent mixed methods study

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ABSTRACT

Objective: High-fidelity simulation (HFS) has positive effects on different learning outcomes in nursing education. The aim of the study was to develop a comprehensive understanding of the added value of HFS building on traditional learning methods in the development of self-efficacy in Bachelor of Science in Nursing students caring for adult patients and their families in early palliative situations.

Methods: A convergent mixed methods study was conducted. In the quantitative study section, a quasi-experimental, repeated measures design was applied measuring self-efficacy using the Self-Efficacy-Subscale of the Bonner Palliativwissenstest (BPW) and the Family Nursing Practice Scale (FNPS). In the qualitative study section, a qualitative descriptive study design was applied. Mixed methods meta-inferences were generated by a joint display table.

Results: The added value of HFS concerning strengthening nursing student's self-efficacy in early palliative care and family systems care was confirmed. The expanded findings were the strengths of HFS with the possibility for students to reflect on their performance and synthesize new insights, as well as the importance of students' practical experience to integrate family systems care in symptom management.

Conclusions: HFS strengthens students in their future role as nurses caring for adult patients and their families in early palliative situations.

Key Words: High-fidelity simulation, Added value, Self-efficacy, Undergraduate nursing education, Palliative care, Familycentered nursing, Family systems care

1. INTRODUCTION

High-fidelity simulation (HFS) uses a computerized manikin to simulate a patient situation as realistic as possible. Every scenario is followed by a structured debriefing of students' performance.^[1] This method provides nursing students with the possibility to learn through an experiential approach^[2] and in a transformative way^[3,4] by self-reflection. HFS can generate different statistically significant positive learning outcomes regarding the development of nursing competence.^[5–8]

The overarching nursing education goal is, that students can apply their acquired competencies in clinical practice. Stu-

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dents' self-efficacy, their belief in their own ability to manage challenging situations,^[9] is crucial to reach this educational purpose.^[10] HFS can facilitate the development of self-efficacy.^[7,11–13]

The aim of palliative care is to enhance the quality of life of terminally ill patients and their families by using holistic symptom management.^[14] Families are people who support one another and are emotionally in touch with each other.^[15] Applying family systems care and building an active partnership with patients, families, and health professionals can improve healthcare outcomes.^[16] Although working with families is an integrative component of palliative care, it may remain challenging for healthcare professionals. Even graduated nurses feel insecure sometimes about their interaction skills with families and how to involve families in care planning.^[17] Thus, the development of self-efficacy regarding palliative care and family systems care is pivotal for nursing students.

According to Masso et al.,^[18] the continuum of terminally ill people and their families can be described in five phases. During the first, stable phase, signs and symptoms of the ill person are under control. The second, unstable phase is characterized by an increase of signs and symptoms leading to an urgent change in treatment. In the third, deteriorating phase, patients' functional status declines. During the fourth, terminal phase, death is expected within days. In the fifth phase, the bereavement of the family, post death support is required.

Quality palliative care starts with high quality palliative nursing education, which HFS is part of.^[19] Previous studies describe the use of simulation learning for undergraduate nursing training in the fourth, terminal or so-called end-oflife-phase of palliative care with high-fidelity manikins alone, or standardized actors, or both in combination. Different positive learning outcomes like attitude towards dying, satisfaction and self-confidence were measured.^[20-23] Regarding pediatric palliative care in the terminal phase, the results of Cole and Foito^[24] underline the importance of the simulation experience for nursing students regarding symptom management, communication with the parents, and aspects of family systems care like appreciating emotions and thoughts. In the same setting, Clark and Lippe^[25] found significant improvements regarding self-efficacy of nursing students in communication with the parents and the child.

However, no study explored the added value of HFS on selfefficacy in Bachelor of Science in Nursing students regarding palliative care and family systems care of hospitalized adults and their families in early palliative situations, where the patient is not immediately dying. The purpose of this study was to develop a comprehensive understanding of this added value. The research question was: What is the added value of HFS building on traditional learning methods for the development of self-efficacy in Bachelor of Science in Nursing students regarding early palliative care and family systems care in hospitalized adults and their families?

1.1 Theoretical framework

The theoretical framework explains the pedagogical background of the study.

Experiential learning

The pedagogical approach of HFS bases on the 4-stage cycle of experiential learning.^[2] The first stage corresponds to the practical experience during the scenario. Reflective observation (second stage) happens through peers observing the student's performance. The guided self-reflection during the debriefing of the performance leads to abstraction and conceptualization (third stage). Active experimentation and testing implications of the discussed concepts is the fourth stage and possible due to repetition of the scenario.

Transformative learning

Mezirow's^[3,4] theory of transformative learning emphasizes the importance of self-reflection to change dysfunctional beliefs. In HFS, self-reflection is part of the debriefing. Its structured procedure reveals student's subjective theories that were guiding their actions. These theories, expanded and transformed through the debriefing, can lead to new problem-solving strategies.

Self-efficacy

Self-efficacy can be achieved through four sources,^[9] which are all represented in HFS: Own experiences of success (students who are active in the scenario), observation of good experiences made by peers (vicarious experience of the observers), verbal encouragement in a dialogue (debriefing), and awareness of one's own feelings (debriefing).

2. METHODS

A convergent mixed methods study was conducted. According to Creswell and Plano Clark,^[26] the convergent mixed method design is a merger of quantitative and qualitative results with the aim of best understanding the research problem. It leads to an increased confidence in the validity of the findings. In the quantitative study section, we used a quasi-experimental, repeated measures design without control group.^[27] In the qualitative study section, we applied a qualitative descriptive study design.^[28] The participants were Bachelor of Science in Nursing students in the fourth semester from a university of applied sciences in Switzerland. All of them had already participated once in a HFS in the second semester. Inclusion criteria were the successful completion of the theoretical courses in palliative care and family systems care and, for the qualitative study section, the participation in the quantitative study section.

2.1 Data collection

Data were collected between June and October 2022. The timeline of the data collection process is shown in Figure 1.

In the quantitative study section, data were collected using the web-based software REDCap^(R).^[29] Self-efficacy was measured at four times (see Figure 1) regarding palliative care with the Self-Efficacy-Subscale of the Bonner Palliativwissenstest (BPW),^[30] regarding family systems care with the German version of the Family Nursing Practice Scale (FNPS).^[31] The quantitative data collection is described in detail elsewhere.^[27]



Note. BPW = Self-Efficacy-Subscale of Bonner Palliativwissenstest, FNPS = Family Nursing Practice Scale



The qualitative data were collected during the week after the students had performed the HFS. Three focus group interviews with 6-8 students per group lasting 90 minutes each were conducted by two co-authors. A semi-structured interview guide with open ended questions based on the theoretical framework of self-efficacy was applied. The interviews were audio recorded and transcribed verbatim.

2.2 Intervention

The HFS scenario is about a hospitalized adult palliative cancer patient in the second, unstable phase of palliative care (simulation manikin, voice given by an actress) and her sister (second actress). During the scenario, an unexpected symptom exacerbation with the necessity to manage holistic aspects of the symptom happened. 5-6 students went through two consecutive scenarios, which differed from each other due to the psychosocial reaction of the actresses. Both scenarios were immediately followed by a structured debriefing. Two different students had active roles in each of the scenarios while the others were in the role of observers. More details concerning the intervention are explained elsewhere.^[27]

2.3 Data analysis

Regarding the quantitative study section, we calculated mean scores for the BPW- and the FNPS-items. A linear mixed model was fitted to the mean BPW- and FNPS-score. The statistical software R version 4.2.1 was used. Quantitative data analysis is described in detail elsewhere.^[27]

Qualitative data were analyzed applying inductive content analysis^[32] using MAXQDA 2022.^[33] First, the data were paraphrased and summarized in inductive categories.

Secondly, an explanatory analysis was conducted to gain an in-depth understanding of the data. Thirdly, a structuring analysis was applied to elaborate the main- and subcategories and the relations among these same. The analysis was regularly discussed with several co-authors.

Mixed methods data analysis

The quantitative and qualitative results were merged and interpreted using a side-by-side joint display table. Furthermore, overarching themes and mixed methods meta-inferences were generated. Meta-inferences are statements related to the results, where they converge or relate to each other (confirmation), diverge (discordance), produce more complete understanding (expansion), and/or where no explanations for differences between quantitative and qualitative results are found.^[26] The joint display table has been discussed with different co-authors.

The visual model for the convergent mixed methods design (see Figure 2) shows the procedures and products of quantitative and qualitative data collection and analysis. Furthermore, procedures and products regarding the merging of the results and the interpretation are explained.

2.4 Ethical considerations

Ethical approval was not required (Cantonal Ethical Committee Kanton Zürich, Switzerland, Req-2022-00417), as the study does not fall within the scope of the Swiss Human Research Act. Additionally, there is a formal statement from the Research Committee for Scientific and Ethical Questions of the UMIT TIROL - Private University for Health Sciences and Health Technology (no. 3057). All procedures were performed in accordance with institutional guidelines and relevant laws. Each participant has given written informed consent to the quantitative and the qualitative study section, respectively. The students were informed verbally and in writing that participation would not have any impact on their further education.



Note. BPW = Self-Efficacy-Subscale of Bonner Palliativwissenstest; FNPS = Family Nursing Practice Scale; HFS = high-fidelity simulation; n = numbers; % = percentages; SD = standard deviations; SE = standard errors; CI = confidence interval

Figure 2. Visual model for the convergent mixed methods design: Procedures and products

3. RESULTS

In the quantitative study section, the mean age of the 46 participants was 23.2 years (minimum 20, maximum 37). 36 (78.3%) students were female, 9 (19.6%) male and 1 (2.2%) divers. The linear mixed model was statistically significant regarding BPW and FNPS. There were statistically significant BPW-contrasts between t1 and t3 ($p \le .0001$), t1 and t4 (p = .0012) as well as t2 and t3 (p = .0112). Regarding FNPS, there were statistically significant contrasts between t1 and t3 (p = .0019) as well as between t1 and t4 (p = .0198). More details on these quantitative results are described elsewhere.^[27]

Only two of the single FNPS-items show statistical significance concerning the contrasts between t2 and t3 (after courses/before HFS and immediately after HFS): Item 1 "confidence level of working with families" (estimate -1.44, SE .48, 95% CI (-2.67; -0.21), p = .0136), and item 5 "feeling comfortable in initiating family involvement in nursing care

planning" (estimate -1.27, SE .44, 95% CI (-2.39; -0.14), p = .0195). For the other items of FNPS and all items of BPW, there is no statistically significant difference concerning the contrast between t2 and t3.

In the qualitative section of the study, 22 students participated. Their age ranged from 20-36 years (mean = 23). 72.8% (n = 16) were female, 22.7% (n = 5) male, and 4.5% (n = 1) divers. The three main categories and 7 subcategories showed the process students go through during HFS by (1) immersing in HFS, (2) experiencing learning achievements and (3) establishing themselves in a professional role. Therefore, (1a) general conditions of the HFS like psychological safety had to be shaped so that students were (1b) able to engage in the scenario. The HFS enabled the students to (2a) apply the acquired theoretical knowledge, (2b) reflect on the performance, and (2c) try out new approaches. In doing so, they became (3a) aware of their limits and (3b) experienced mastering the transition from a student to a nurse.

Table 1. Joint display of results,	overarching themes,	and mixed met	thods meta-inferences	s: Palliative care a	nd family
systems care					

Quantitative results ^[27]			Qualitative results		
Instrument	Mean Scores	Contrasts of time, <i>p</i> -values	Qualitative subcategories	Overarching themes	Mixed methods meta-inferences
Self-Efficacy-Subsca le of Bonner Palliativwissenstest (BPW): Self-efficacy in palliative care	t1: 2.88 t2: 2.96 t3: 3.14 t4: 3.10	t2-t1: .3508 t3-t1: <0001 t3-t2: .0112 t4-t1: .0012 t4-t2: .1193 t4-t3: .8563	 1a) Immersing in high-fidelity simulation: Shaping general conditions "The feedback is tailored to you personally. I mean, in all other forms of teaching, you never get that. That is unbelievably valuable – you get it from lecturers who train you, you get it from students who are on the same level as you, and then from actors from whom you almost never get it in practice." (F1, Pos. 73) "The situation itself did not feel like a palliative situation to me. So, I was more in an acute situation, with symptoms I had to treat." (F2, Pos. 89) "The scenario was quite palliative () it was an acute situation but in palliative care one experiences these situations ()." (F2, Pos. 94) 1b) Immersing in high fidelity simulation: Engaging in high-fidelity simulation "It is not like: Ah, you did it wrong. Or like the communication training we had and then you look a lot at the negative aspects. () you pick up the positive points and see what you can add. And that helps me personally in learning 		Confirmation: Added value of high fidelity simulation concerning strengthening student's self-efficacy in palliative care and family systems care Discordance: Palliative focus of the scenario
Family Nursing Practice Scale (FNPS): Self-efficacy in family systems care	t1: 2.57 t2: 2.33 t3: 2.08 t4: 2.14	t2-t1: .2500 t3-t1: .0019 t3-t2: .2567 t4-t1: .0198 t4-t2: .6445 t4-t3: .9295	 and to be able to accept criticism." (F3, Pos. 6) 2a) Experiencing learning achievement: Applying the acquired knowledge "Now during high-fidelity simulation, it was like one step higher [Note: than in the course] ()." (F1, Pos. 111) "It is holistic, while in the individual course the focus is completely on one topic." (F1, Pos. 118) "The expertise has also become better for me () because I synthesized, and one begins to create connections." (F2, Pos. 28) "() a simulation like this has a big learning effect on these two topics [Note: family systems care and palliative care]." (F3, Pos. 108) 2b) Experiencing learning achievement: Reflecting on the performance "() and one begins to reflect much more. Not just: Oh my God, I have done it badly now. But yes, I have acted like this because I thought, it is like this () it also helps to self-reflect very much." (F1, Pos. 85) 2c) Experiencing learning achievement: Being able to try out new approaches "So, it [Note: high-fidelity simulation] really creates a place where you can try something out and see how it works. And without it causing any damage or anything. Yes." (F3, Pos. 94) 3a) Establishing oneself in a professional role: Becoming aware of one's limits "And you also get to know your limits. () you do not learn that when you are sitting in the lecture hall." (F2, Pos. 64) 3b) Establishing oneself in a professional role: Mastering the transition from a student to a nurse "And my self-efficacy is improved, and I feel strengthened in my role as a nurse in the future when I do these simulations." (F3, Pos. 20) "() it's one more experience that gives you () a lot of security for the practice and self-efficacy: Hey, I can do this and yes it works" (F3 Pos. 176) 	Development of self-efficacy in palliative care and family systems care	Expansion: Strength of high-fidelity simulation are different interrelated topics, holistic scenario, debriefing (personal feedback from peers, actors, lecturers with also focus on success factors), possibility to try out alternative approaches, reflect performance, connect knowledge, synthesize insights. Feel strengthened in the role of future nurse. No explanation: Difference of contrasts of time t3-t2 BPW vs. FNPS

Note. BPW: Self-efficacy 1 = low and 4 = high; FNPS: Self-efficacy 1 = high and 5 = low; t1 = before courses, t2 = after courses, t3 = immediately after high-fidelity simulation, t4 = 3 months after high-fidelity simulation

Mixed methods results

An excerpt of the joint display of quantitative and qualitative results, overarching themes and mixed methods metainferences is shown in Tables 1 and 2. The comparison of quantitative and qualitative results generated three overarching themes: (1) Development of self-efficacy in palliative care and family systems care (BPW and FNPS [see Table 1]), (2) development of self-efficacy in working with families

(FNPS item 1, statistically significant regarding the contrasts between t2 and t3 [see Table 2]), and (3) development of self-efficacy in involving families in nursing care planning (FNPS item 5, statistically significant regarding the contrasts between t2 and t3 [see Table 2]). Three confirmed, one discordant, and two expanded findings were generated under the overarching themes.

Quantitative results		·	Qualitative results	•	
FNPS item	Means	Contrasts of time, <i>p</i> -values	Qualitative subcategories	Overarching themes	Mixed methods meta-inferences
Item 1: Confidence level in working with families	t1: 2.67 t2: 2.48 t3: 2.05 t4: 2.05	t2-t1: .4257 t3-t1: .0001 t3-t2: .0136 t4-t1: .0003 t4-t2: .0250 t4-t3: .9996	 2a) Experiencing learning achievement: Applying the acquired knowledge "I think when you are in the simulation like that, you learn a lot more () than when I go through some theoretical models and learn how to have family systems care conversations with patients." (F1, Pos. 108) 2b) Experiencing learning achievement: Reflecting on the performance "I think () the self-confidence as well as the self-efficacy, which is actually ultimately strengthened. The experience of handling and relationship building, which was also really looked at in depth, how it was experienced, what did I implement, what did I consciously do based on the design, theories, and models that I got to know and what not." (F2, Pos. 22) 3b) Establishing oneself in a professional role: Mastering the transition from a student to a nurse "My confidence in dealing with clients and patients has further increased, so I would underline that, so I feel like I can do that, or I can do it that like that." (F2, Pos. 23) "And just because you take small little pieces of all models and theories [Note: e.g. instructing relatives], it doesn't mean that we haven't progressed using our knowledge, I think that actually shows that we have progressed in our knowledge because we then also apply it either consciously or unconsciously, so it is actually like even more beautiful because we have internalized it so much that we now simply use it without thinking about it much." (F2, Pos. 26) 	Development of self-efficacy in working with families	Confirmation: Added value of high-fidelity simulation in strengthening self-efficacy through the practical experience of working with families
Item 5: Feeling comfortable in initiating family involvement in nursing care planning	t1: 2.47 t2: 2.25 t3: 1.76 t4: 2.03	t2-t1: .7298 t3-t1: .0011 t3-t2: .0195 t4-t1: .1680 t4-t2: .6597 t4-t3: .3443	 2a) Experiencing learning achievement: Applying the acquired knowledge "Yes, and there I had () a learning effect when family members are there, how to do this or how my colleagues did it." (F1, Pos. 117) 2b) Experiencing learning achievement: Reflecting on the performance "Often in many settings, the typical family systems care, where you take an hour to have a conversation, it is not possible. In an emergency you just () apply part of the family systems care, I would never have thought of it and it got pointed out to us, to me. Because with me it was always like that during the course [Note: course in family systems care]: Yes, but that's not possible at all in everyday life, I can't take an hour and sit down." (F1, Pos. 116) "() I think we have become much more aware of the added value of family systems care for us (,") (F2, Pos. 92) "Because let's be honest nowadays, the reality is, so my first impulse was: Go outside the door [Note: family member] quickly for a moment. () so yes, it would not have been the goal, or it is not the goal of family systems care. It's actually nice to then be able to involve the family members." (F3, Pos. 44) 3b) Establishing oneself in a professional role: Mastering the transition from a student to a nurse "I realized that I want to be more involved with the relatives." (F1, Pos. 130) "And then to realize: Hey having this person [Note: family member] there and being able to guide them (). I had the feeling that it was great - so I also thought back to the knowledge that we learned in family systems care, it can also be extremely helpful () to include the whole family or all the relatives. And then also to experience that it's ok in this situation." (F3, Pos. 138) 	Development of self-efficacy in involving families in nursing care planning	Confirmation: Added value of high-fidelity simulation concerning feeling more comfortable with family involvement in nursing care planning Expansion: Added value of high-fidelity simulation concerning the practical (partially vicarious) experience, that family systems care can be implemented in daily nursing care during management of acute symptoms (not comprehensible for a part of students during courses without being in concrete nursing situation).

Table 2. Joint display of results, overarching themes, and mixed methods meta-inferences: "Working with families" and "Involving families in nursing care planning"

Note. FNPS: Self-efficacy 1 = high and 5 = low; t1 = before courses, t2 = after courses, t3 = immediately after high-fidelity simulation, t4 = 3 months after high-fidelity simulation

The confirmed findings were the added value of HFS concerning strengthening student's self-efficacy in palliative care and family systems care, in working with families, and in feeling more comfortable with family involvement in nursing

care planning.

The discordant finding concerns the palliative focus of the scenario. Inspite of the statistically significant increase of

self-efficacy in palliative care over all times of measurement, a part of the students did not recognize palliative aspects in the scenario, but acute symptom management.

The expanded findings were the strength of HFS through the interrelated topics of palliative care and family systems care in the holistic scenario, the possibility to try out alternative approaches, as well as the debriefing with the possibility to reflect on the performance, to connect theoretical knowledge, and to synthesize new insights. The students felt strengthened in their role of future nurses due to the experience of HFS. Furthermore, another expanded finding was the impact of the simulation experience on implementing family systems care in daily nursing routine even during the management of acute symptoms.

There was no explanation found for the differences of contrast of time between times of measurement t2 and t3 of BPW (p-value = .0012) versus FNPS (p-value = .2567).

4. DISCUSSION

This study confirms the added value of HFS building on traditional learning methods for the development of self-efficacy in Bachelor of Science in Nursing students caring for adult patients and their families in early palliative situations. The importance of the practical experience of working with families and feeling more comfortable with family involvement in nursing care planning is particularly emphasized. Our results are consistent with other mixed methods studies describing HFS scenarios in the terminal phase of palliative care.^[34–36]

Even though the five phases of palliative care^[18] were a substantial topic in the palliative care course, some students identified the scenario situated in the second, unstable phase of palliative care as not palliative according to the qualitative results. It is one of the frequently mentioned prejudice of laypeople and even healthcare professionals, that palliative care consists mainly or only of end-of-life care.^[37,38] The lectures held during the palliative course and the participation in the HFS scenario do partly seem not to be effective to change this subjective theory of some students.

The expanded findings show that students feel strengthened in their role as future nurses regarding palliative care and family systems care. This aspect is also described in a mixed methods study assessing the gain of communication skills through HFS.^[39] Furthermore, our mixed methods metainferences show the strength of HFS due to the standardized debriefing as another expanded finding. The central components of the debriefing like reflecting, connecting theoretical knowledge, and transforming one's own subjective theories are part of the sources of self-efficacy^[9] as well as of Mezirow's^[3,4] theory of transformative learning. Standardized debriefing is also recommended in the Healthcare Simulation Standards of Best Practice^[40] and by Nunes and Harder^[19] concerning palliative simulation. They emphasize the importance of student's possibility to express their emotions and feelings during the debriefing, also mentioned as one of the self-efficacy sources by Bandura.^[9]

Another expanded finding concerning the added value of HFS is the students' positive experience of being able to integrate family systems care in the management of acute symptoms. Before HFS, family members were not seen as a resource in such a situation by a part of our students, even though it was a key component of the lectures in palliative care and family systems care. This loss of abstractness of family systems care is also shown by Wyrostok et al.,^[36] who describe an increase of student's self-efficacy regarding the therapeutic alliance between nurse, patient and family through the simulation. Furthermore, the importance of the reflective observation of positive experiences by peers is emphasized by this expanded finding. The possibility to observe, how peers integrate the family member in patient care, led some students to realize the possibilities of this approach. This aspect of vicarious learning is also mentioned in the experiential learning theory,^[2] in the self-efficacy theory,^[9] by Clark and Lippe^[25] and by Fernández-Basanta et al.,^[41] who describe observing in addition to doing and reflecting as main sources of learning.

As no explanation was found in the qualitative results, why our HFS scenario seems to be less effective in developing the self-efficacy regarding family systems care than regarding palliative care (difference of contrasts of time between t2 and t3), the only explanation for this result remains the difference in the structure of the course palliative care versus the one in family systems care.^[27]

Limitations

Limitations of this study are the predetermined maximum study population as we did not include students of other semesters or other universities. As the participation in both study sections was voluntary, it could be that the students who participated in the qualitative study were even more committed and enthusiastic about HFS than the students only participating in the quantitative section. Therefore, this sample is not representative of the population and may limit generalizability. Furthermore, the results were not evaluated based on the students' roles in the simulation (active participants versus observers) due to the high-fidelity simulation procedure (most students assumed both roles during the two sessions) and the small sample size.

5. CONCLUSION

HFS in undergraduate nursing education offers students the opportunity to connect and try out the theoretical knowledge acquired in lectures, reflect on the performance, synthesize new insights, and transform their subjective theories. This is crucial to develop self-efficacy. Thus, students feel empowered in the role as future nurses.

This study supports prior research concerning the added value of HFS for the development of self-efficacy in Bachelor of Science in Nursing students and adds results regarding palliative care and family systems care of hospitalized adults and their families in early palliative situations. Future research should focus more on the early phases of palliative care, other learning outcomes, and cast a light on the impact of student's role in the scenario (active or observer role).

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AUTHORS CONTRIBUTIONS

Conceived idea: SH, FG; Study design: SH, EH, FG, IR, DD Data collection: SH, EH, FG; Data analysis: SH, EH, AM, FG, IR, DD; Manuscript writing: SH; Contributions to the revision of the manuscript: EH, AM, FG, IR, DD.

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The authors declare that there is no conflict of interest.

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DATA SHARING STATEMENT

No additional data are available.

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