Volume 20 Issue 54
Originally issued as F9



Global Journal of Medical Research: F
Diseases
Volume 20 Issue 9 Version 1.0 Year 2020
Type: Double Blind Peer Reviewed International Research Journal
Publisher: Global Journals
Online ISSN: 2249-4618 & Print ISSN: 0975-5888

Development and Validation of a *Yoga* Module for Adolescents with Type 1 Diabetes

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Objective: This study developed and validated a Junior yoga module (JYM) for adolescents with T1D.

Materials and Method: The content validity of JYM for adolescents is assessed by a panel of 20 experienced yoga experts. The JYM for adolescents with T1D is developed in the form of the tailor-made yoga practice supported by classical texts and research evidence. All the 41 practices in the JYM, is discussed and rated as:



Strictly as per the compliance and regulations of:



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Sonu Maurya [α], Dr. Itagi Ravi Kumar [σ], Dr. Amit Singh [ρ] & Dr. R. Nagaratna [ω]

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i. Not essential,
ii. Useful but not essential,
iii. Essential.

Lawshe's formula is adopted to arrive at the content validity ratio (CVR) after obtaining the ratings.

Result: Data analysis revealed that out of the 41 JYM practices, 27 JYM exhibited significant content validity (cut-off value: 0.49, as calculated by applying Lawshe's formula for the CVR).

Conclusion: The present study suggested that the JYM for adolescents with T1D is valid with good content validity. However, future studies must determine the feasibility and efficacy of the developed JYM module for adolescents with T1D.

Keywords: autoimmune disorder, type 1 diabetes, yoga and diabetes, yoga, adolescents.

I. Introduction

Most adolescent patients with type 1 diabetes (T1D) do not meet treatment goals, which increases their risk for diabetes-related complications; therefore, finding ways to improve adherence to therapy is crucial (Patel *et al*., 2018). Type 1 diabetes (T1D) develops in genetically predisposed people as a result of the destruction of the pancreatic beta cells caused by an autoimmune insulitis (Briscoe *et al*., 2007; Sharma, 2017). Increased thirst, frequent urination, bed-wetting in children and adolescents who previously didn't wet the bed during the night, extreme hunger, unintended weight loss, irritability and other mood changes, fatigue, and weakness, blurred vision are some major symptoms (Fowler, 2008; Kalra *et al*., 2013).

Adolescents experience significant physiological and psychosocial changes during this developmental stage, including increased insulin resistance related to pubertal hormones, significant weight gain, higher insulin needs, and independence from parents. Unfortunately, this newfound autonomy often results in problems with T1D. It may further exacerbate poor glycemic control. Besides, adolescents with chronic hyperglycemic conditions may be more likely to engage in high-risk behaviors, such as drug and alcohol use, cigarette smoking, etc. (Comeaux, 2010; Patel *et al*., 2018; Weitzman *et al*., 2015).

Yoga is a mind-body intervention and comprises physical practice (*äsana*), breathing technique (*präëäyäma*), and meditation, and relaxation techniques. *Yoga* is a popular complementary and alternative medicine modality worldwide (Falkenberg *et al*., 2018).

Many studies have reported several health benefits of *yoga* for a clinical condition such as asthma, diabetes, pulmonary tuberculosis, epilepsy, fibromyalgia, and arthritis (Cramer, 2015; Gowtham, 2018; Hongasandra, 2017; Lin Yin *et al*., 2011; Nagothu, 2015; Patil, 2019; Ross & Thomas, 2010; Shantakumari *et al*., 2013; Vijayakumar, 2018; Vinutha *et al*., 2015; Zivdar, 2014), and consistent effects especially on circulating inflammatory markers (Falkenberg *et al*., 2018), improvements in physical fitness, immune activity (Kosuri & Sridhar, 2009), improved beta-cell function (Raj, 2016), and reduced stress as physiological mechanisms for beneficial effects of yoga on the immune system in adolescents (Sahay, 2007; Mohan *et al*., 2005; Szablewski, 2014).

II. Quality of Life and Type 1 Diabetes

Children with type 1 diabetes mellitus (T1DM) have to deal with a complex and demanding daily treatment regime, which can harm the quality of life (QoL) of these patients (Rasoul *et al*., 2013). Although children and adolescents with T1DM have to live with a demanding treatment regime, overall results revealed that their generic QoL is not impaired compared to healthy peers (Duru *et al*., 2015). Young adults with Type 1 diabetes mellitus are a high-risk group with suboptimal glycemic outcomes when compared with older adults with Type 1 diabetes (Ambler *et al*., 2006). Management

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is challenging because of psychosocial issues; for example, body image perceptions (Neumark *et al*., 2002), the increased incidence of psychiatric illness (Bernstein *et al*., 2013), eating disordered (Quick *et al*., 2012), and impaired quality of life (Kibbey *et al*., 2013; Ingerski *et al*., 2010). Some studies suggest that low glycemic variability may be associated with lower quality of life, negative moods, blood glucose fluctuations (Penckofer *et al*., 2012). A meta-analysis of 27 studies demonstrated that depression is majorly associated with hyperglycemia for type 1 diabetes (Lustman *et al*., 2000). Moods such as anxiety and anger often accompany depression with type 1 diabetes (Peyrot & Rubin, 1997); anxiety is associated with poor glycemic control (Anderson *et al*., 2002). Anger is also linked to depression (Pasquini *et al*., 2004). It is associated with glucose fluctuation and poorer self-management of hyperglycemia for persons with type 1 diabetes.

For persons with type 1 diabetes, high glucose values suggest to impact mood negatively, positive mood rating decreased, whereas negative mood ratings increased, tension and anger is reported to be higher in type 1 diabetes individuals in the hyperglycemic range compared with those in the hypoglycemic range with continuous glucose monitoring (CGM) (Hermanns et al., 2007). However, glycated hemoglobin (HbA1c) has been the standard for assessing glycemic control, glycemic variability (Hirsch, 2005).

III. Yoga and Immune System

Yoga is an ancient mind-body practice that is increasingly recognized to have health benefits in a variety of clinical and non-clinical conditions (Falkenberg *et al*., 2018). Among various types of *yoga*, emphasizing both physical and mental training, and typically consists of *yoga* poses, breathing, and meditation (Nagendra, 2003). It is stated that *yoga* not only increased physical endurance but also reduced pro-inflammatory markers such as interferon γ (INF-γ), interleukin-6 (IL-6), interleukin-2 (IL-2), and stress level (Pullen *et al*., 2008). Based on these results, *yoga* practice is required to achieve consistent effects, especially on circulating inflammatory markers (Falkenberg *et al*., 2018), improvements in physical fitness, immune activity (Kosuri & Sridhar, 2009), improved beta-cell function (Raj, 2016), and reduced stress as a physiological mechanism for beneficial effects of *yoga* on the immune system (Sahay, 2007; Mohan *et al*., 2005; Szablewski, 2014). The practice of *yoga* reduced inflammation and smaller autonomic, endocrine, and inflammatory response to the stressors and novices. The *yoga* practice demonstrated more rapid declines (recovery) in stress hormone and proinflammatory cytokines production and better glycemic control in T1D (Sreedevi, 2017). *Yoga* is a cost-effective option in the treatment and prevention of autoimmune disorder, with data from several studies suggesting that *yoga* and other mind-body therapies can reduce stress-related hyperglycemia and have a positive effect on glycemic control, balancing harmonizing the body, mind, and emotions. Increasing evidence suggests that *yoga* practice tackles the pro-inflammatory mechanisms of T1D and helps in controlling autoimmune disorders (Amita *et al*., 2009; Author, 2019; Dubey *et al*., 2014; Sharma *et al*., 2013, 2014).

Previous studies on *yoga*, physical activity (Chimen *et al*., 2012; De Lima *et al*., 2017), and exercise (Herbst *et al*., 2006; Reddy *et al*., 2018) have demonstrated that these practices changed glycaemic variation, improved mental health and quality of life (QoL) in autoimmune diseases (Falkenberg *et al*., 2018).

a) Materials and methods

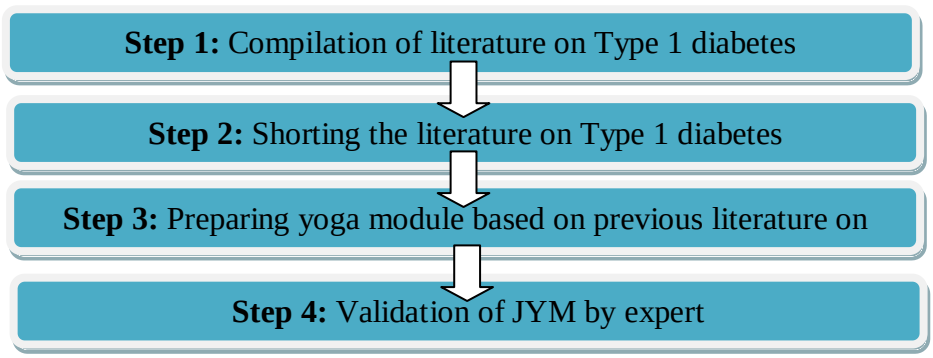
The content validity of JYM for adolescents with T1D is assessed by a panel of 20 experienced *yoga* experts. The JYM for children and adolescents with T1D is developed in the form of tailor-made *yoga* practices that are supported by classical texts and research evidence.

All the 41 practices in the JYM, is discussed and rated as

i. Not essential,
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Lawshe's formula is adopted to arrive at the content validity ratio (CVR) after obtaining the ratings.

Figure



The steps followed to execute the above-mentioned methods are as follows:

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Step 1: Compilation of literature on yoga and diabetes

a. In this phase, we reviewed traditional and contemporary *yoga* texts.
b. Research paper on the use of *yoga* in diabetes, immune and metabolic disorders, including modern scientific reviews of T1D, were identified using different search engines such as Pub Med and Google Scholar. Indexing terms such as *yoga* immune disorder, metabolic disorder, and *yoga*, and diabetes. All experimental studies that used *yoga* as the therapy for diabetes are included.

Step 2: Shorting the literature on yoga and diabetes

A summary of the literature is tabulated for a quick overview. Then, studies done on different practices and published in journals as a scientific background is extracted.

Step 3: Preparing yoga module based on previous literature on yoga and diabetes

Based on classical texts and research evidence a detailed protocol with tailor-made practices is developed.

Step 4: Validation of JYM by expert

Yoga experts with clinical experience are provided with this complete module (who had either a doctorate or Doctor of medicine degree in *yoga*, with a minimum of 5 years experience or a Master's degree in *yoga*/ *yoga* therapist, with a minimum of 7 years experience). These experts were requested to participate in evaluating the content validity for the proposed instrument on a 3-point scale rated as follows: (i) not essential (has no role in improving any symptoms or the quality of life of patients with T1D), (ii) useful but not essential (useful in improving general wellbeing, but the benefits are not specific to T1D symptoms), and (iii) essential (very effective for T1D).

An expert panel, including 20 experts with the above qualifications, involved for determining the content validity. Experts in *yoga* therapy with clinical experience ⩽5 years) were also considered *yoga* experts. Among the 20 experts, more than ten has previously applied *yoga* therapy in patients with diabetes and were already using most of the practice included in this module.

The CVR for the total scale was computed based on expert validation. According to Lawshe's formula, if more than half of the panelists indicate that an item is essential, then that item has the minimum content validity. The CVR for our scale was ⩾0.49, which was considered satisfactory for a panel of 20 experts.

b) Statistical Analysis

The cut-off value of 0.49 is calculated by applying Lowshe's formula for CVR (Lawshe, 1975). The mean CVR across the item indicated the overall test content validity.

$$CVR = \frac{n_e - N/2}{N/2}$$

Where,
Ne = total number of panelists indicating "essential" for each practice.
N = total number of panelist

IV. Result

The data analysis showed that out of 41 JYM practices, 27 indicated significant content validity in (Table 1). 14 practice (Table 2) had a CVR score of below 0.49, indicating low content validity.

Table 1: Practice with a CVR score of⩾0.49

SL. no.	Practice Name	CVR	SL. no.	Practice Name	CVR
1	*Vyäghra Çväsana*	0.9	15	*Pavanamuktäsana*	1
2	*Pärçva Ürdhva Hastäsanä*	0.5	16	*Bhujaìgäsana*	0.9
3	*TääsanaPratyägama*	1	17	*Tiryaka Bhujaìgäsana*	0.6
4	*bhunamanPratyägama*	0.7	18	*Dhanuräsana*	1
5	*Naukäsaïcälana*	0.9	19	*Setubandhäsana*	0.6
6	*Süryanamaskära*	1	20	*Matsyäsana*	0.5
7	*Trikoëäsana*	0.7	21	*Naukäsana*	0.7
8	*Tiryaka Trikoëäsana*	0.8	22	*Uttänapädäsana*	0.6
9	*Pärçvakoëäsan*	0.5	23	*Çaväsana*	1
10	*Vakräsana*	1	24	*Anuloma- Viloma*	1
11	*Maëòükäsana*	0.9	25	*Bhrämaré*	0.8
12	*Garbhäsana*	0.7	26	Guided Meditation on the Visualization of Pancreas	0.7
13	*Üñöräsana*	0.7	27	*Agnisärakriyä*	0.7
14	*Bäläsana*	0.5			

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Table 2: Practices with a CVR score of ≤ 0.49.

Sl. No	Practice	CVR
1	*Sasàìgäsana Çväsana* (Rabit breathing)	0.3
2	*Citrapataìga* (Butterfly)	0.1
3	Dorsal stretch	0.2
4	*Täääsana*	0.1
5	*Véräsana*	0.4
6	*Jänusiräsana*	0.3
7	*Vyäghräsana*	0.4
8	*Ardhapädäpaççimottänäsana*	0.3
9	*Kürmäsana*	0.3
10	*Bhardväjäsäna*	0.3
11	*Makaräsana*	0.4
12	*Çalabhäsana*	0.3
13	*Haläsana*	0.4
14	*Kapälabhäti*	0.4

Table 3: Yoga module for Adolescents with T1D

Special *Yoga* Module for Type 1 Diabetes Mellitus

Sl. no	Practice (*Saà skrata*)	Practice (English)	Round	Time, minutes
1.	**Starting Prayer (` shnavrt u.....)**			
2.	**Specific *Kriyä* for Type 1 Diabetes mellitus**			
a.	*Agnisära kriyä*		3	5
3.	**Specific loosening practice for Type 1 Diabetes mellitus**			
a.	*Pärçva Ürdhva Hastäsanä*	Side bending	5 each side	1
b.	*Täòäsanä Pratyägama*	Mountain pose twist	5 each side	1
c.	*Bhünaman Pratyägama*	Greeting the earth pose with twist	5 each side	1
d.	*Naukäsaï cälana*	Rowing the boat flow	5	1
4.	**Specific breathing practice for Type 1 Diabetes mellitus**			
a.	*Vyäghra Çväsana*	Tiger breathing	5 up & down	1
5.	***Süryanamaskära* (Slow speed 3 to 6 round according to an individual's capacity)**			
6.	**Specific relaxation after breathing**			
a.	*Çaväsana* (with "A-kar" chanting)	Quick relaxation technique	1	1-2
7.	**Specific Standing *Äsana* for Type 1 Diabetes mellitus**			
a.	*Trikoëäsana*	Triangle Pose	1	1
b.	*Tiryaka Taòäsanaa*	Mountain Pose	1	1
c.	*Pärçvakoëäsana*	Side Angle Pose	1	1
8.	**30 second relaxation after each *Äsana* *(as per the condition)***			
9.	**Specific Seating *Äsana* for Type 1 Diabetes mellitus**			
a.	*Vakräsana*	Spine twist pose	1	1
b.	*Maëòükäsana*	Frog pose	1	1
c.	*Garbhäsana*	Embryo pose	1	1

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d.	*Ürdhvä sana*	Camel pose	1	1
e.	*Bäläsana*	Child pose	1	1
f.	*Pavanamuktäsana*	Wind relieving pose	1	1
10. 30 second relaxation after each *Äsana* *(as per the condition)*				
11. Specific Supine *Äsana* for Type 1 Diabetes mellitus				
a.	*Setubandhäsana*	Bridge pose	1	1
b.	*Matsyäsana*	Fish pose	1	1
c.	*Naukäsana*	Boat pose	1	1
d.	*Uttänapädäsana*	Raised leg pose	1	1
12. 30 second relaxation after each *Äsana* *(as per the condition)*				
13. Specific Prone *Äsana* for Type 1 Diabetes mellitus				
a.	*Bhujaìgäsana*	Cobra pose	1	1
b.	*Tiryaka Bhujaìgäsana*	Swaying cobra pose	1	1
1. Specific relaxation after *Äsana* for Type 1 Diabetes				
a.	*Çaväsana*	Dep relaxation technique	1	5
2. Specific Pranayama for Type 1 Diabetes mellitus				
a.	*Anuloma- Viloma*	Alternate nostril breathing	9	5
b.	*Bhrämaré*	Bee sound	9	5
3. Specific Meditation for Type 1 Diabetes mellitus				
a.	Guided Meditation on the Visualization of Pancreas		1	10
4. Closing prayer (sv ÉvN uz io n>.....)				
				Time duration – 60 min

V. Discussion

In the present study, we developed a JYM for adolescents with T1D by choosing specific yoga practices from the traditional literature and scientific studies on yoga to target certain symptoms of adolescents with T1D. Validated JYM by the yoga experts taking their suggestions is finalized. Similarly, an effort was made to retain only those practices which were rated by all experts as useful. The yoga practices are included, as suggested by the experts. All the experts opined that these practices should be easy for children and adolescents with T1D. Relaxation practice is also included between the session as per the advice of the experts. So, The matching of yoga practices with symptoms of adolescents finalized after reviewing traditional literature (Saraswati, 2004; Mukibodha, 2000). The present study was closely associated with previous studies on the validation of JYM (Ahilan, 2015; Amita *et al*., 2009; Author, 2019; Balaji *et al*., 2012; Baro, 2016; Berger *et al*., 1977; Chandrasekhar, 2009; Dubey *et al*., 2014; Eda, 2014; Kudigra & Ns, 2018; Kumar, 2017; Kumar, 2015; Metri *et al*., 2017; Prabhu *et al*., 2015; Raj, 2016; Raveendran *et al*., 2018; Rodrigues, 2016; Sharma *et al*., 2013, 2014; Shrivastava *et al*., 2017; Vaishali et al., 2012; Campaigne, 1985).

In the present, there is no previous study that focused on the validation of a yoga module for T1D. This study is done in two phases:

a) We are designing the yoga module for T1D, b) expert validation of the module for T1D.

In the first phase, the JYM was designed based on literature reviews of traditional text reference and recent research publications. We did not find any direct source for yogic practice capable of improving T1D symptoms. However, the latest Hatha *Yogic* text has increasingly emphasized on improving health through different *yogic* practices. Besides, recent findings on T1D reported by several schools of *yoga* have helped in the formulation of a *yoga* module for T1D. The CVR calculation for all 41 practices is completed in our *yoga* module. Of these, 27 practices (CVR≥0.42) were included in the validated yoga module (Table 1). The remaining fourteen poses (Table 2) (CVR <0.49), namely Butterfly, Tadasana, (0.1), Dorsal stretch (0.2), Rabit breathing, Janusirasana, Ardhapadapaschimittanasana, Kurmasana, Bharadwajasana, Salabhasana (0.3), Veerasana, Vyaghrasana, Makarasana, Halasana, Kapalbhati (0.4) were used as a complementary for important posture to stimulate the pancreases and synchronization along with body and mind. These practices were slightly challenging for T1D therapy. Apart from these fourteen practices, the 27 poses included for T1D treatment; thus, the final CVR satisfied the minimum value, as per Lowshe's CVR.

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Similar to any other exercise protocol, an ideal yoga module consists of frequencies, intensities, duration, and progression. Determining the appropriate mode depends upon the patient's preference and safety issues associated with the T1D or other conditions. Keeping in view the safety and patient's ability the duration and frequency of the pose customized for practice (Table 3).

Çithilikaraëa Vyäyäma (Loosening Practice) include in this module helped in loosening the joint and strengthen the muscles, which consequently helped in improving the function of abdominal organs (Dhirendra, 1973).

Süryanamaskära (Sun Salutation), A series of dynamic *yoga* posture in a specific sequence, stimulate insulin production through brain signaling, exerting beneficial effects on the glycemic outcome (Raj, 2016).

Yogäsana (Yoga Posture) rejuvenates of pancreatic cells through the alternating abdominal contraction and relaxations involved in *yoga* practice. Improves blood supply to muscles, enhances insulin receptors expression in the muscles, with forwards bending pose, manage and pressurizing the pancreas, stimulating insulin secretion (Ahilan, 2015; Eda, 2014).

Çuddhikriyä (Cleansing Processes), *Agnisära Kriyä* (stimulating the digestive fire) involves pulling the abdomen in and snapping it backward and forward while holding one's breath. Helps in the producing of insulin and controlling glucose levels in the blood; the effect of this action massage the internal organs and increases blood flow to the area (Kudigra, 2018; Raveendran *et al*., 2018).

Präëäyäma (regulated breath), *Anulomvilom* (alternate nostril breathing), improves components of health-related fitness, cardio respiratory endurance, flexibility, and body fat percentages.

Bhrämaré (humming bee breath), a soothing and calming effect on the mind, improves mental and physical health(Author, 2019; Sreedevi, 2017).

Dhyäna (Meditation): This leads to beneficial psychological effects, such as a faster reaction to stimuli and less prone to various forms of stress, anxiety reduction, and blood pressure control. Meditation on the *Manipur Chakra* (solar plexus), visualization of the pancreas during meditation, gives positive effects on sugar levels (Balaji *et al*., 2012; Eda, 2014; Raj, 2016).

VI. Conclusion

A comprehensive and traditional texts based *yoga* module was developed and validated by 20 experts who agree to most of the practices. Whoever, future studies must determine the feasibility and efficacy of T1D.

Sources of funding
None

Conflict of interest
None

Acknowledgments

The authors acknowledge all the experts for offering their comments and inputs to develop this module.

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