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App-based Yoga of Immortals: A Novel, Easy-to-use Intervention in the Management of Urinary Incontinence

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Conflict of interest statement

Ishan Shivanand was employed by the company, *SYC Infinite*. *SYC Infinite* did not provide any funding for this study and had no role in the study. The remaining authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Supplementary Materials

Supplementary Information Tables: Table S1: Demographic details of the study population. Table S2: YOI module audio and video time, Table S3: Improvement based on PGI-I scale, Table S4: Effect of YOI intervention on selected mean ICIQ-UI-SF scores and ICIQ-LUTS-QOL scores. Table S5: Correlation between ICIQ-LUTS-QOL scores vs 'how much this bother you?'

Supplementary Information Text and Figures: About ICIQ-UI-SF, ICIQ-LUTS-QOL and PGI-I scale, Figure S1: ICIQ-UI-SF questionnaire,

Supplementary information Questionaries: ICIQ-LUTS-QOL 08/04 questionaries

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Institutional Review Board Statement

The study was approved by the Institutional Review Board, University of Cincinnati, Cincinnati, Ohio (IRB approval no: 2020-0494), United States of America.

Informed Consent Statement

Informed consent was obtained from all subjects involved in the study.

Data Availability Statement

The data presented in this study are available on request from the corresponding author. The data are not publicly available due to Ethical Concerns.

Abstract

Objective

To study the effectiveness Yoga of Immortals (YOI) intervention in participants with urinary incontinence (UI) of all types. YOI uniquely combines specific yogic postures, breathing exercises, sound therapy & meditation and is practiced by many for general well-being.

Materials and Methods

In this App-based cohort study, a survey was sent to the YOI app subscribers. Those who identified with UI and consented were sent the ICIQ-UI- SF (for mean symptom score & severity of UI), and the ICIQ-LUTS-QOL (for impact of UI on QOL) Questionnaires at baseline, 4, and 8 weeks. Global impression of improvement was assessed by PGI-I scale.

Results

258/422 participants (18-74 years) were included and showed significant decrease in mean scores on the ICIQ-UI-SF (4.06 ± 0.24 at baseline; 2.90 ± 0.22 at 4-weeks [$p \leq 0.001$] and 3.44 ± 0.23 at 8 weeks [$p \leq 0.001$]) and ICIQ-LUTS-QOL (28.36± 0.74 at baseline; 24.46± 0.70 at 4-weeks [$p \leq 0.001$] and 25.78± 0.70 at 8 weeks [$p \leq 0.001$]). Additionally, the 55-60 year subgroup also had significant decrease in mean scores on ICIQ-LUTS-QOL (25.06 ±1.20 at base line; 21.69 ± 1.07 at 4 weeks [$p \leq 0.01$] and 22.28 ± 0.96 at 8 weeks [$p \leq 0.01$]).

Conclusion

YOI intervention resulted in significant improvement in mean scores on ICIQ-LUTS-QOL; ICIQ-UI-SF; frequency and severity of urinary leak; and daily life activity. Majority of the participants felt 'very much better' on PGI-scale. Being app- based, it has the added advantage of the ability to be used anytime and anywhere.

Introduction

Urinary incontinence (UI) is the involuntary loss of urine, and a common problem in community-dwelling adults [1]. An estimated 25-45% of all adult women have UI, whereas 15% of middle-aged or older women have UI [2]. UI is associated with poor quality of life and difficulties in social, psychological, and sexual functioning [3]. Despite the high success rates of UI treatments, only <20% of affected women seek medical attention [4].

The initial approaches to UI management are lifestyle interventions, bladder training, and pelvic floor muscle training (PFMT), which are used either alone or combined with other interventions [5, 6]. Although a systematic review on the effectiveness of PFMT in women with stress UI (SUI) and mixed UI (MUI) has been published including 19 long-term studies, meaningful comparisons cannot be made among different studies to provide pooled long-term cure rates due to methodological variabilities [7]. Some of the barriers to effective PFMT include lack of patient understanding of pelvic muscles, inability to focus on the specific pelvic floor muscles, and lack of motivation to complete the treatment. Insurance non-coverage and negative patient perception of efficacy are the other factors for patient nonparticipation in a PFMT program [7].

Drawbacks of other current treatments for UI, such as medications (for urgency UI) and bulking agents & midurethral sling surgery (for female stress UI) include adverse effects of medications and possible complications of invasive surgery, respectively. Therefore, there is a need for novel treatment options that are easy, convenient, safe, and effective.

Yoga breathing, relaxation, and muscle control techniques may strengthen the pelvic floor [8-10]. Specific yogic poses that are believed to be helpful and have been tested include the *Utkatasana* (chair pose), *Trikonasana* (triangle pose) and the *Malasana* (squat pose) [11]. Yoga may help improve general body alignment, flexibility, strength, control and awareness, all of which are thought to strengthen the pelvic floor muscles [9]. Yoga may, therefore, be utilized as an alternative method of PFMT. Yoga may also additionally address mental health and quality of life issues through potential effects on depression, stress and anxiety, and this adjuvant benefit of yoga may facilitate patients manage their other associated medical conditions [12-15]. A pre-post trial of in-person (by yoga instructor and continence nurse specialist) PFMT with adjunctive

Hatha yoga in women with SUI reported improvement in the UI [16]. One randomized trial of *Iyengar yoga* for UI, provided in-person training to the participants by an experienced, certified instructor and assistant, noted promising results in SUI and UUI [11]. However, despite the benefit in UI, the *Iyengar yoga* needs in-person training, which significantly adds to the overall treatment cost.

The *Yoga of Immortals* (YOI) app-based intervention is a comprehensive behavioral intervention program, involving a combination of pelvic floor muscle exercises, specific breathing exercises, sound therapy (chanting), specific yogic postures, and meditation. YOI intervention has recently been shown to be effective in anxiety, depression, insomnia, and UI in the community setting, either as a 'stand-alone' or adjunctive treatment modality [12-14, 17].

Performing the exercises in the comfort of one's home can be attractive, appealing, reduce medical and travel expenses, and simplify logistics. With increasing smartphone availability, mobile health apps are growing to offer new health interventions, which can increase adherence to therapy. The app-based YOI intervention is a unique and innovative app-based treatment modality. YOI also involves specific exercises aimed at pelvic floor muscles, lower urinary tract, and related energy centers. We, therefore, studied the effectiveness of YOI in UI. To our knowledge, this is the first study assessing the effectiveness of mobile app-based YOI intervention in UI in both women and men on a global scale with participants from 23 countries. We studied the effectiveness of YOI in UI of all types in a group of non-targeted male and female participants in a community setting without the need for healthcare provider supervision.

Methods

Study design

Participants in this prospective cohort study were emailed questionnaires including demographics and questions on UI to determine whether they met the study criteria. For this study, self-reported urinary leakage by the participants was considered as UI (**Table S1, Figure 1**).

Inclusion Criteria

- Men and women aged >18 years with UI (of all types)

- Agree to provide informed consent
- Willing to participate, and dedicate 30 min daily to follow the intervention daily for 8-weeks, and complete the questionnaires as required

Exclusion Criteria

- Pregnant women
- Those who did not complete the questionnaires

Study approval

The study was approved by the Institutional Review Board, University of Cincinnati, Cincinnati, Ohio, United States of America (IRB approval number, 2020-0494).

Assessment scales

After returning the informed consent and the preliminary questionnaires, all participants answered a questionnaire that recorded background participant characteristics and lifestyle. They completed three validated questionnaires: the *International Consultation on Incontinence Modular Questionnaire, UI Short Form* (ICIQ-UI-SF) (**Figure S1**) to evaluate symptom severity; the International Consultation on Incontinence Questionnaire, *Lower Urinary Tract Symptoms Quality of Life* (ICIQ-LUTS-QOL) to evaluate condition-specific quality of life [18]; and participant global impression of improvement (PGI-I) to rate their improvement in UI condition, the latter on a scale from 1 (very much better) to 7 (very much worse) [19]. For the ICIQ-LUTS-QOL questionnaire, there are 19 questions that are scored as 1 (for 'never'), 2 (for 'sometimes'), 3 (for 'often'), and 4 (for 'all the times'). Therefore, the minimum total ICIQ-LUTS-QOL score for any participants will be 19, because even a 'never' answer gets a score of 1. Further description about the scores and list of questions is provided in supplementary information. Selected participants with UI were emailed these validated questionnaires at baseline (Pre-survey), during YOI intervention (at 4 weeks, Mid-survey), and after YOI intervention (at 8 weeks, Post-survey).

Primary outcomes

- The mean symptom score and severity of UI were assessed by the ICIQ modular questionnaire, ICIQ-UI-SF at baseline, 4 weeks, and 8 weeks.

- The impact of UI on the QOL was assessed by the disease-specific QOL questionnaire, ICIQ-LUTS-QOL at baseline, 4 weeks, and 8 weeks.

Secondary outcomes

- Patients' global impression of improvement (PGI-I) was measured during and after the YOI intervention.
- Incontinence episode frequency was assessed from the ICIQ-UI-SF. A reduction in leakage episodes of >50% was considered clinically relevant.

YOI intervention

The mobile app-based YOI program (for iOS and Android devices) was designed to provide clear instruction to participants in the video and audio format (**Table S2**). The app helped participants to precisely practice specific YOI protocols to improve bladder control. YOI intervention is meant to stimulate the energy centers, including those for urinary control, and open up energy meridians in the body. YOI emphasizes on precise anatomical alignment and awareness of particular body structures during practice, specific breath work to facilitate/enhance detoxification, sound therapy (chanting), and specific meditation practices. YOI also includes a core set of specific yogic postures to engage the pelvic floor and passive postures to promote relaxation.

Statistical analysis

The survey responses were exported into *Microsoft excel* file, and then organized, and processed using *Microsoft excel* functions. The data quality was ensured with human verification and implementation of attention checks throughout the survey. *GraphPad Prism 8* was used for statistical analysis. The demographics of study participants are shown in number and percentage. The descriptive statistics are shown in number, difference (δ) and percentage difference (%δ). The comparative statistics for mean scores for different categories was done using *Analysis of variance* (ANOVA) with post hoc test. Repeated One-way ANOVA was applied with multiple comparisons using *Tukey's test* for baseline comparison with mid or post. Non-parametric one-way ANOVA (Kruskal-Wallis test) was applied with multiple comparison using Dunn's test for reduction in total score based on PGI-scale. The p-value <0.05 and 95% confidence interval was considered as statistically significant. The baseline score of participants served as the control for

comparison. Linear regression was for used for correlation between 'total scores' and '*how much this bother you?*' of total baseline scores, mid scores and post scores.

Results

In this prospective cohort study, we demonstrated that the mobile app-based YOI intervention resulted in significant improvements in both symptom scores (for urinary frequency, extent of urine leak, and interference with daily life activities due to urine leak) and condition-specific QOL (**Table 1**, **Table 2 and Figure 2**) in most of the age groups. The improvement was highly significant in both primary and secondary outcome measures. The participants with more severe leakage at baseline experienced even greater improvement. Most of the demographic categories in our study showed significant improvement in mean ICIQ-LUTS-QOL score at 4-weeks and 8-weeks.

258 participants (18-74 years) were included in the study. There was significant decrease in mean scores on the ICIQ-UI-SF (4.06 ± 0.24 at baseline; 2.90 ± 0.22 at 4-weeks [$p \leq 0.001$] and 3.44 ± 0.23 at 8 weeks [$p \leq 0.001$]) and ICIQ-LUTS-QOL (28.36± 0.74 at baseline; 24.46± 0.70 at 4-weeks [$p \leq 0.001$] and 25.78± 0.70 at 8 weeks [$p \leq 0.001$]). Most of the participants said they felt very much better on PGI-I scale, 59.69% at 4-weeks and 49.61% at 8-weeks of YOI intervention (**Figure 2, Table S3**). The reduction in both ICIQ-UI-SF and ICIQ-LUTS-QOL mean scores were highest for those participants who reported that they felt very much better or much better on PGI-I scale (**Figure 2**). After treatment, participants experienced improved urinary frequency, extent of urine leak, pad usage, and interference with daily activities from urine leak resulting in better quality of life and improved mental health (**Table 2, Figure 2**). Throughout study, we noted an increase in number of participants in the 'no UI' category by 21% during YOI practice at 4-week and 9.69% after YOI at 8-week. The significant reduction in mean scores was observed for stress UI and mixed UI (**Figure 2, Table 1**). The mean LUTS, QOL score and participants' response to question, "*how it bothers you?*" had positive liner correlation (**Figure 2**). The correlation between each question and participant's response to the question "*how it bothers you?*" is also shown in **Table S4**.

Discussion

The YOI mobile app based intervention was evaluated in the present study as a first-line treatment for UI of all types in both men and women that wanted to try an easily accessible, self-management treatment. Most of the participants in this study were women (94.5%) similar to that reported in the literature [20, 21]. Participants in the present study represent a clinically relevant group in a primary care setting, as they had moderate to severe leakage (97.5%) and all the participants actively desired treatment. Majority of study participants were in the 18-44 age group and had a minimum of Bachelor's degree in education. Education level, however, has not been noted to affect the ability to learn or perform correct pelvic floor muscle contractions [22]. The outcome measures and questionnaires used in the study are validated and well established, which enabled comparisons with other studies.

The YOI intervention in our study resulted in significant improvement in mean scores on ICIQ-LUTS-QOL; ICIQ-UI-SF; frequency and severity of urinary leak; daily life activity & stress urinary incontinence. ICIQ-LUTS-QOL scores also improved in the elderly sub-group. Majority of the participants felt 'very much better' on PGI-scale. The results in our study were similar to those reported in different PFMT programs, indicating that the improvement in our study was not a mere placebo effect. For example, three PFMT programs had mean baseline ICIQ-UI-SF scores ranging from 8.6-12.0, which reduced by 3.0-4.5 after treatment [23-25]. In two of these studies [24, 25] participant ages (32-72 years and 35-60 years) were similar to those in our study; the third study [23] included older women. In another study with 250 participants (mean age 48.6 years, baseline ICIQ-UI-SF score 10.4), also reported reductions in mean score with PFMT [26]. Previously, for conservative treatments, the minimum essential differences were established for the ICIQ-UI-SF (2.5) and the ICIQ-LUTS-QOL (3.7) [27]. Improvements above these levels are considered clinically relevant at the group level. The improvements in the ICIQ-LUTS-QOL scores in our study were 3.9 at 4-weeks and 2.58 at 8-weeks. The difference in the improvement between 4-weeks and 8-weeks is likely due to the variation in YOI module content, which varied every week. Additionally, the 55-60 year age subgroup also had significant decrease in mean scores on ICIQ-LUTS-QOL (25.06 ±1.20 at base line; 21.69 ± 1.07 at 4 weeks [$p \leq 0.01$] and 22.28 ± 0.96 at 8 weeks [$p \leq 0.01$]).

To our knowledge, this is the first study to assess the effectiveness of mobile app-based YOI intervention in UI in both women and men at a global scale with participants from 23 countries. In addition, this is the first app-based intervention study for UI (all types) in a prospective cohort setting. The strength of this app-based YOI is that it can be practiced at subject's own time and place of preference. During the study, there were no major technical problems or disruptions, and we made no changes to the app. We did not have any missing outcome values because we only selected those participants in analysis who completed all surveys (pre-mid and post) on time. This reduced the risk of bias that could be introduced when imputing values. To facilitate future implementation of the app, we simulated a routine setting, with minimal contact between the participants and the research team.

About 94% participants followed up at week-4, while 63% followed up at week-8. The reason 30% loss to follow up from week 4 to week 8 could not be identified. However, contributing factors could be the participants contracting other diseases, difficulty in managing time to practice YOI daily, and difficulty to practice YOI by the elderly, among others. Also, as the study was conducted during COVID-19 pandemic, the loss to follow up could be because of COVID-19 infections in participants.

During a follow-up period of 8 weeks, it is possible that some participants will have improved due to spontaneous remission. The annual remission rate of SUI has previously been calculated to be 7% [28]. Based on this, very few participants in our sample might have improved due to spontaneous remission.

In a 10 year follow up after Kegel pelvic floor muscle exercises for SUI, Cammu et al. noted that out of 45 women, physiotherapy was successful in 24 patients (53% of study population) [29]. Considering such outcomes and that of other published studies (21-23), we believe there are indications that the YOI may be more effective than the commonly used Kegel exercises, albeit our study was not designed to compare YOI with Kegel pelvic floor muscle exercises.

In this study, we showed that it is possible to effectively treat UI without face-to-face contact. For the future, it is important to establish subgroups that benefit the most from YOI, and how the intervention can best be integrated in everyday practice. It might also help unload primary healthcare, as costs are likely to be lower than face-to-face treatments. Even if efficacy is equal to or even lower than face-to-face treatments, the low delivery cost may make mobile

app-delivered treatment a more cost-effective alternative. Future studies may also focus on the cost-effectiveness and the long-term effects of the YOI intervention.

The reminder function in the YOI mobile app may also increase adherence to the intervention. In PFMT study [30], the most common barrier to adherence was difficulty remembering to perform the exercises. After instructions at clinical visits, only 31.5% of participants continued daily exercises after 3 months.

In the present study, we have shown that mobile app (iOS and Android) based YOI intervention is effective for UI in the short term. Currently, we are continuing to assess its use and effectiveness. Evaluations of the long-term adherence and effects are ongoing, as are studies on the cost-effectiveness of app-based treatment.

YOI may be an adjunctive treatment option in community dwelling individuals with UI who are inclined towards these practices. This may be a plausible option with the aging baby boomers that are technologically savvy. Future prospective and randomized studies including a larger number of participants in different age groups with the intervention specifically customized to the subgroups, at different functional levels, are warranted to further corroborate the benefits of YOI noted in our study.

Limitations of the present study are that this is not a randomized controlled trial. Although standardized face-to-face treatment would have been an option, we wanted the intervention to be accessible for anyone from all over the world, including those from remote areas and from areas with inadequate healthcare access. Furthermore, it is possible that the study is underpowered. However, at the time of power calculation, there were few published studies of yoga using the outcome measures that we used in our study. Another limitation of this study may be that we did not compare the YOI app-based treatment with another active treatment or care-as-usual. However, there is currently no ‘gold standard’ treatment for UI, and care-as-usual varies in different settings. In addition, we wanted to provide an easily and widely accessible treatment to anyone who chooses, for whatever reason, not to seek in-person health care.

Conclusion

App-based Yoga of Immortals (YOI) intervention is a new, promising, and effective alternative treatment for UI in men and women of all age groups. YOI was effective for urinary incontinence yielding significant and clinically relevant improvements without in-person visits to

the healthcare provider. Being app- based, it has the added advantage of the ability to be used anytime and anywhere. It may increase access to care and serve as first-line treatment for UI. The app can potentially increase adherence to treatment and may be used to complement other treatments. Moving forward, we plan to standardize and customize the YOI mobile content to focus lower urinary tract exercises and assess the long-term effectiveness of YOI in the management of urinary incontinence.

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Figure legends

Figure 1. A) Flowchart of the YOI intervention study process. It includes sending email to all participants' before YOI intervention (Pre-survey), during YOI intervention (Mid-survey), and after YOI intervention (Post-survey), and followed by selection based on selection criteria to get the final number of participants for data analysis. 'n' is a number of responses recorded from users after removing duplicate entries. B) Worldwide graphical distribution (%) of participants in YOI intervention for urinary incontinence. n = 258, after matching participants.

Figure 2. A1-A6) ICIQ-UI-SF scores on baseline (pre), during (mid) and post YOI intervention. B1-B4) ICIQ-LUTS-QOL scores on baseline (pre), during (mid) and post YOI intervention. Non-parametric one-way ANOVA (Kruskal-Wallis test) with multiple comparison using Dunns' test was applied. Reduction in total score based on PGI-I scale. C1) ICIQ-UI-SF baseline to mid. C2) ICIQ-UI-SF baseline to post. D1) ICIQ-LUTS-QOL baseline to mid. D2) ICIQ-LUTS-QOL baseline to post. E1-E3) Graphical correlation between 'total scores' to 'how much this bother you?' for pre, mid and post YOI intervention on ICIQ-LUTS-QOL questionnaire. 'r' is Pearson coefficient of correlation, 'R^2' is regression coefficient, and 'CI' is confidence interval. Repeated measure one-way ANOVA was applied with multiple comparison using Tukey's test. *p ≤ 0.05, *** p ≤ 0.001, **** p ≤ 0.0001. n=258

Figure S1. ICIQ-UI-SF questionaries [18].

Table 1. Baselines ICIQ-LUTS-QOL scores of participants among different categories.. Scores are depicted as mean ± SEM. Repeated measure one-way ANOVA was applied with multiple comparison using Tukey's test. *p ≤ 0.05, **p ≤ 0.01, *** p ≤ 0.001, **** p ≤ 0.0001. n = 200

Category	**Mean LUTS-QOL scores**		
	Pre	**Mid**	**Post**
	Gender		
Female (*n* = 189)	27.85 ± 0.72	23.72 ± 0.65****	25.38 ± 0.69****
Male (*n* = 11)	37.09 ± 4.48	37.18 ± 5.01	32.55 ± 3.95$^{\#}$
	Age		
18-44 (*n* = 94)	29.64 ± 1.22	26.27 ± 1.24**	26.80 ± 1.13****
45-54 (*n* = 59)	28.93 ± 1.28	23.69 ± 1.02****	26.75 ± 1.28**
55-64 (*n* = 36)	25.06 ± 1.20	21.69 ± 1.07**	22.28 ± 0.96**
65-74 (*n* = 11)	25.18 ± 1.98	22.18 ± 1.77	23.37 ± 2.29
	No of children		
1-2 children (*n* = 138)	27.14 ± 0.78	23.30 ± 0.62****	24.68 ± 0.72****
3-4 children (*n* = 8)	36.00 ± 5.61	24.25 ± 3.80**	29.50 ± 5.80**
Blank (*n* = 54)	30.33 ± 1.61	27.46 ± 1.93*	28.02 ± 1.54*
	Delivery procedure		
Both (*n* = 9)	26.33 ± 2.50	19.56 ± 0.67*	21.56 ± 1.35*
Cesarean section (*n* = 51)	26.67 ± 1.45	23.29 ± 1.09***	24.08 ± 1.26***
Normal Delivery (*n* = 86)	28.56 ± 1.05	23.95 ± 0.83****	25.97 ± 1.02****
Blank (*n* = 54)	29.98 ± 1.61	27.19 ± 1.93*	27.78 ± 1.55*
	Coffee or tea		
<2 cups/day (*n* = 115)	28.34 ± 0.96	24.21 ± 0.90****	25.63 ± 0.93****
2-4 cups/day (*n* = 53)	28.32 ± 1.45	23.49 ± 1.11****	25.38 ± 1.22***
>4 cups/day (*n* = 5)	30.60 ± 4.74	23.00 ± 3.21	24.80 ± 3.23
No (*n* = 27)	28.11 ± 2.08	27.70 ± 2.67	27.37 ± 2.17
	Smoking		
No (*n* = 194)	28.32 ± 0.74	24.38 ± 0.70****	25.85 ± 0.71****
Yes (*n* = 6)	29.67 ± 5.84	27.00 ± 6.04	23.33 ± 3.40

Table 2. Change in number, percentage of participants, and mean scores for selected ICIQ-UI-SF and ICIQ-LUTS-QOL score at week 0 (pre or baseline), week 4 (mid), and week 8 (post) of YOI intervention. n = 258. Repeated measures one-way ANOVA with multiple comparisons using Tukey's test was applied with 95% confidence interval. and * p ≤ 0.05, ** p ≤ 0.01, *** p ≤ 0.001, **** p ≤ 0.0001

	Number			%			δ		Mean score		
Leak	**Pre**	**Mid**	**Post**	**Pre**	**Mid**	**Post**	**Mid**	**Post**	**Pre**	**Mid**	**Post**
Urinary leak frequency (from ICIQ-UI-SF)											
Never	79	125	104	30.62	48.45	40.31	17.83	9.69	0.00 ± 0.00	0.14 ± 0.06	0.19 ± 0.07*
Once	123	92	107	47.67	35.66	41.47	-12.02	-6.20	1.00 ± 0.00	0.86 ± 0.07	0.94 ± 0.07
2-3 times a week	29	21	21	11.24	8.14	8.14	-3.10	-3.10	2.00 ± 0.00	1.24 ± 0.18***	1.70 ± 0.19
Once everyday	5	12	14	1.94	4.65	5.43	-2.71	-3.49	3.00 ± 0.00	0.20 ± 0.20***	0.60 ± 0.40***
Several times a day	21	8	12	8.14	3.10	4.65	-5.04	-3.49	4.00 ± 0.00	2.29 ± 0.31****	2.67 ± 0.31****
All times	1	0	0	0.39	0.00	0.00	-0.39	-0.39	5.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00
Extent of urinary leak (from ICIQ-UI-SF)											
None	78	127	100	30.23	49.22	38.76	18.99	8.53	0.00 ± 0.00	0.21 ± 0.08*	0.28 ± 0.08**
a small amount	165	122	145	63.95	47.29	56.20	-16.67	-7.75	2.00 ± 0.00	1.36 ± 0.08****	1.67 ± 0.07****
a moderate	14	9	13	5.43	3.49	5.04	-	-	4.00	2.57 ±	2.86 ±

amount							1.94	0.39	0 ± 0.00	0.33**	0.35*
a large amount	1	0	0	0.39	0.00	0.00	-0.39	-0.39	6.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00
Interference in daily activities due to urine leak (from ICIQ-UI-SF)											
0 (Not at all) to 3	208	233	230	87.21	90.31	89.15	3.10	1.94	0.69 ± 0.06	0.65 ± 0.10	0.70 ± 0.085
4 to 7	17	17	21	6.59	6.59	8.14	0.00	1.55	4.59 ± 0.21	2.65 ± 0.62*	3.47 ± 0.66
8 to 10 (Great Deal)	16	8	7	6.20	3.10	2.71	-3.10	-3.49	8.56 ± 0.20	4.75 ± 0.74***	5.63 ± 0.75**
Different types of UI (from ICIQ-UI-SF)											
No IC	58	114	83	22.48	44.19	32.17	21.71	9.69	0.34 ± 0.23	0.40 ± 0.16	0.55 ± 0.20
Stress IC	128	76	85	49.61	29.46	32.95	-20.16	-16.67	4.03 ± 0.20	2.72 ± 0.26***	3.18 ± 0.25***
Mixed IC	48	44	53	18.65	17.05	20.54	-1.94	1.55	7.65 ± 0.72	5.65 ± 0.67**	6.96 ± 0.67
Urge IC	23	24	35				0.78	5.04	6.04 ± 0.90	4.40 ± 0.82	4.74 ± 0.69
Enuresis#	1	0	2	8.91 0.39	9.30 0.00	13.57 0.78	-0.39	0.39	NA	NA	NA
Depression due to urinary problem (from ICIQ-LUTS-QOL)											
Not at all	200	224	220	77.52	86.82	85.27	24	20	1.00 ± 0.00	1.07 ± 0.02****	1.03 ± 0.01****
Slightly	40	25	28	15.5	9.69	10.8	-15	-12	2.00	1.32 ±	1.48

				0		5			± 0.00	0.07**	± 0.10
Moderately	13	5	5	5.04	1.94	1.94	-8	-8	3.00 ± 0.00	1.85 ± 0.25**	2.08 ± 0.21 **
very much	5	4	5	1.94	1.55	1.94	-1	-0	4.00 ± 0.00	3.00 ± 0.63	3.80 ± 0.20
Anxiety due to urinary problem (from ICIQ-LUTS-QOL)											
Not at all	177	203	195	68.60	78.68	75.58	26	18	1.00 ± 0.00	1.09 ± 0.03**	1.10 ± 0.03 **
Slightly	59	42	49	22.87	16.28	18.99	-17	-10	2.00 ± 0.00	1.46 ± 0.07** **	1.61 ± 0.08 ****
Moderately	12	7	8	4.65	2.71	3.10	-5	-4	3.00 ± 0.00	1.92 ± 0.23**	1.82 ± 0.17 ****
very much	10	6	6	3.88	2.33	2.33	-4	-4	4.00 ± 0.00	3.10 ± 0.35	3.00 ± 0.37
Sleep affected due to urinary problem (from ICIQ-LUTS-QOL)											
Never	171	191	181	66.28	74.03	70.16	20	10	1.00 ± 0.00	1.11 ± 0.03**	1.12 ± 0.03 ****
Sometimes	60	52	61	23.26	20.16	23.64	-8	1	2.00 ± 0.00	1.65 ± 0.08** *	1.70 ± 0.09 **
Often	17	10	12	6.59	3.88	4.65	-7	-5	3.00 ± 0.00	1.94 ± 0.22** *	1.94 ± 0.16 ****
All the times	10	5	4	3.88	1.94	1.55	-5	-6	4.00 ± 0.00	2.3 ± 0.37**	2.90 ± 0.31 *
Wearing pads to keep dry (from ICIQ-LUTS-QOL)											
Never	199	217	214	77.13	84.11	82.95	18	15	1.00 ± 0.00	1.04 ± 0.01*	1.03 ± 0.01

											*
Sometimes	43	27	28	16.67	10.47	10.85	-16	-15	2.00 ± 0.00	1.49 ± 0.09***	1.63 ± 0.09***
Often	6	7	7	2.33	2.71	2.71	1	1	3.00 ± 0.00	2.67 ± 0.49	2.17 ± 0.40
All the times	10	7	9	3.88	2.71	3.49	-3	-1	4.00 ± 0.00	3.3 ± 0.30	3.90 ± 0.10
Urinary symptoms affecting daily life activity (from ICIQ-LUTS-QOL)											
0 (Not at all) to 3	195	228	227	76	88	88	12.79	12.40	0.74 ± 0.07	0.62 ± 0.09	0.72 ± 0.10
4 to 7	30	23	21	12	9	8	-2.71	-3.49	4.93 ± 0.20	2.43 ± 0.35***	3.37 ± 0.46**
8 to 10 (Great Deal)	15	7	10	6	3	4	-3.10	-1.94	8.80 ± 0.22	6.40 ± 0.78*	6.27 ± 0.80**

for enuresis mean score was not applicable due as there are was only one participant in pre. IC: Incontinence; NA: Not applicable

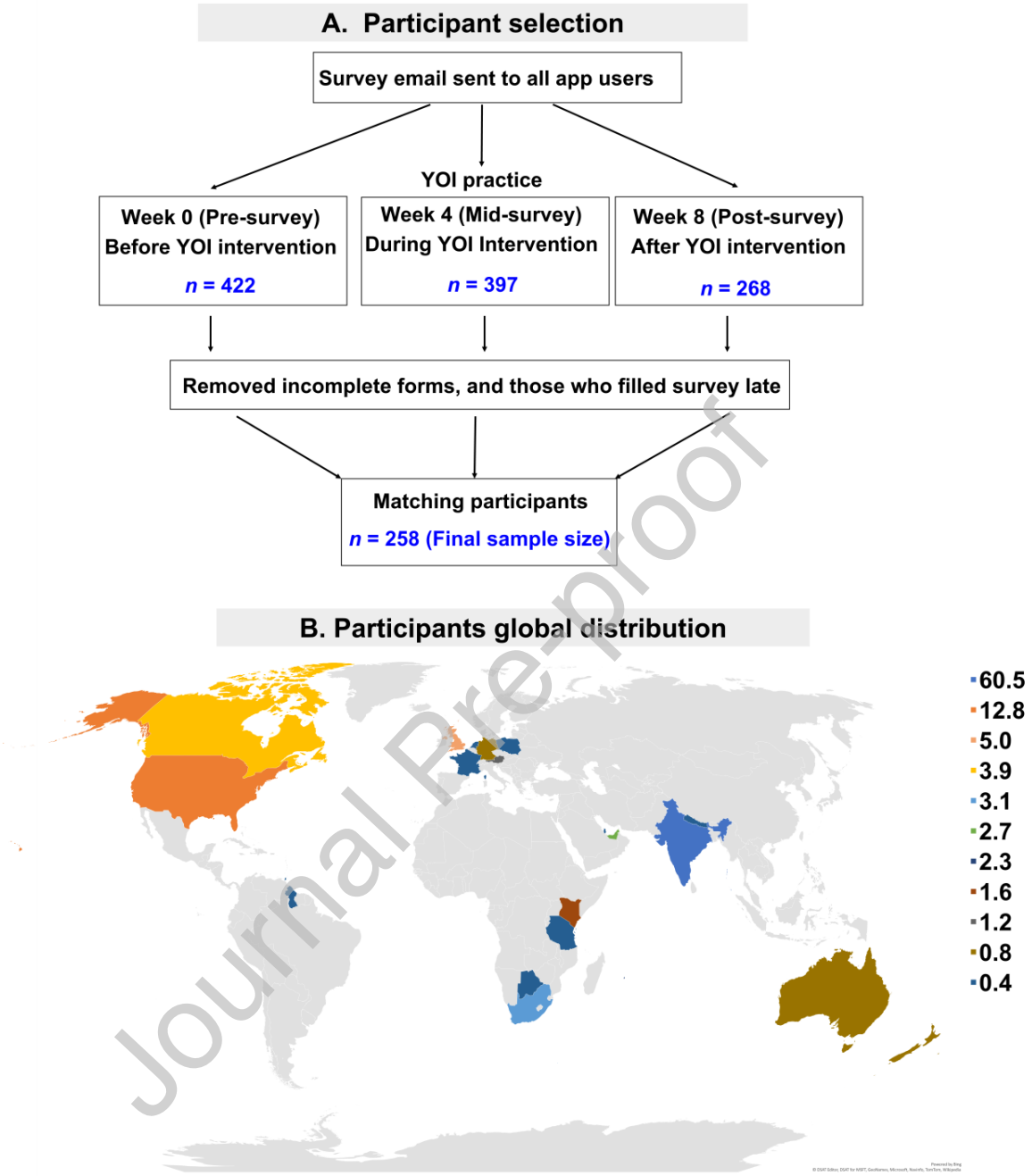

Fig. 1

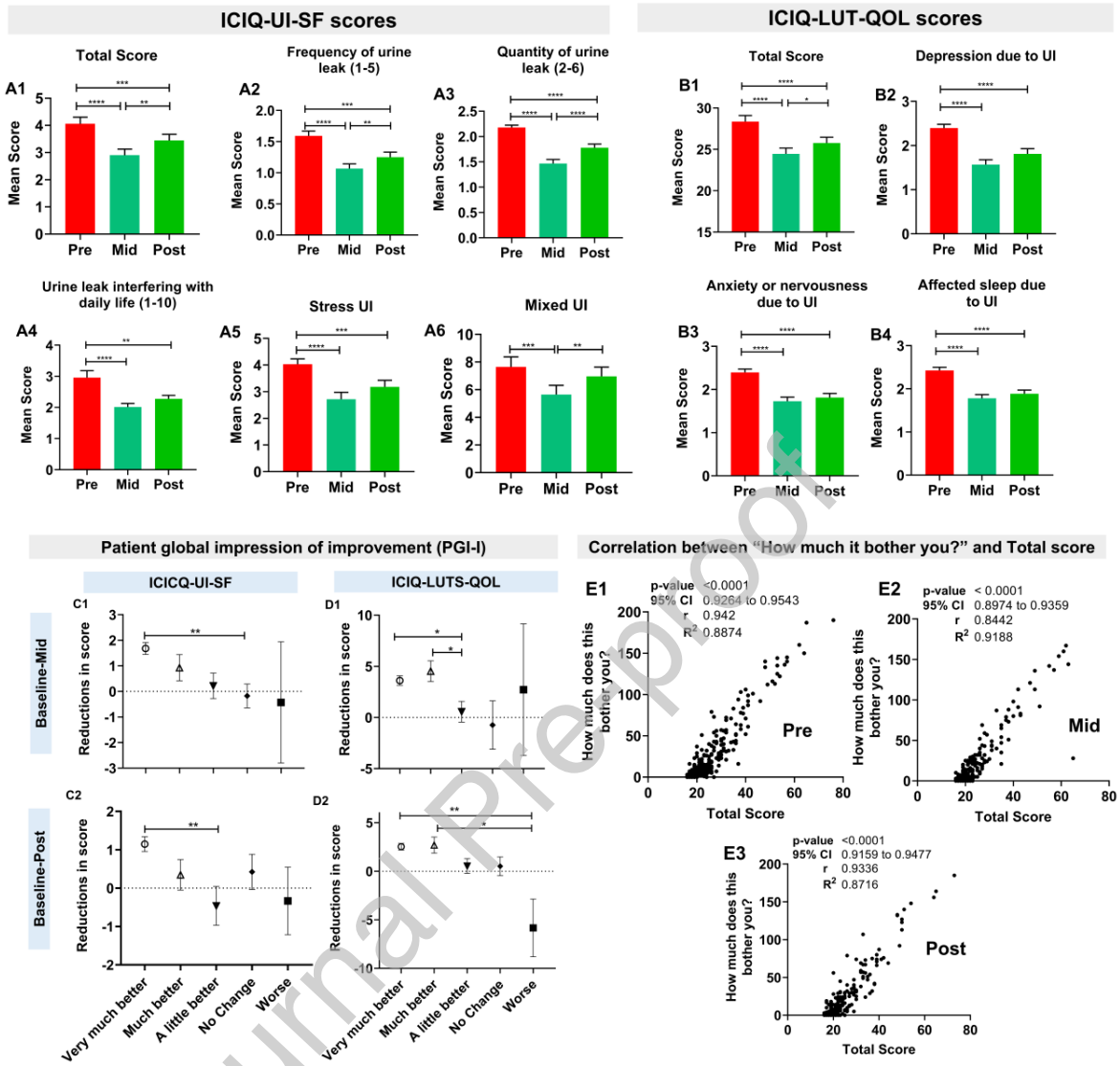

Fig. 2