Utility of Kent’s Repertory in the treatment of candidiasis: An open label, Single arm, interventional clinical trial

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ABSTRACT

Background: Candidiasis is a significant opportunistic infection that adversely affects the quality of life. This study aims to evaluate the effectiveness of individualized homeopathy (IH) in treating Candidiasis using remedies selected from Kent's repertory. Methods: An open-label, prospective, single-arm, non-randomized, non-controlled clinical trial with a pre-post comparison design was conducted at the Repertory outpatient department (OPD) of the National Institute of Homoeopathy in Kolkata, India. Results: The calculated t29 value, obtained through the use of the Numeric Rating Scale (NRS) and Muco-Cutaneous Assessment Questionnaire (MCAQ) scoring scales, was found to be 8.04 or 9.17. Referring to the t-table at a degree of freedom of 29, the critical t-value at α = 0.05 was determined to be 2.05. Since the calculated t-value (8.04 or 9.17) is greater than the table value (2.05) at α = 0.05, the results are considered statistically significant at p ≤ 0.05. The study demonstrates a significant improvement in the pre and post-intervention status of patients enrolled in the clinical trial. Conclusion: This study provides evidence supporting the positive effect of IH, selected based on the principles of Kent's repertory, in patients with various types of candidiasis. The findings indicate a need for further evaluation through randomized control trials (RCTs) with larger sample sizes to confirm and strengthen the results obtained in this study.

Keywords: Candidiasis, Individualized Homoeopathy, Numeric Rating Scale (NRS), Mucocutaneous Candidiasis assessment questionnaire (MCAQ).

INTRODUCTION

Candidiasis is a common fungal infection caused by an overgrowth of Candida, a type of yeast, on the skin and mucous membranes. While most bacteria and fungi on the body are harmless commensals, Candida can become infectious and cause various forms of candidiasis. Cutaneous candidiasis, characterized by red and itchy rashes, is particularly common in the folds of the skin due to increased temperature and moisture in these areas. Additionally, Candida infections can affect the mouth, vagina, and even lead to bloodstream infections in certain cases. [1, 2]

The conventional treatment of candidiasis faces limitations in effectively controlling pathogen growth, primarily due to the high cost of antifungal drugs and the rising occurrence of drug-resistant Candida. Due to these challenges, there is a need for alternative and complementary therapies, including individualized homoeopathy, to provide effective and safe treatment options.
infections. This has created a demand for alternative treatments that can more effectively control the overgrowth of Candida without disrupting the body's normal homeostasis. [3]

In this context, the present study aims to explore the utility of Kent's Repertory, a renowned homoeopathic literature, in the treatment of candidiasis. The study follows an open-label, single-arm, interventional clinical trial design. By utilizing Kent's Repertory, the study aims to identify homeopathic remedies that can effectively address the overgrowth of Candida and treat candidiasis while considering the individualized symptoms and characteristics of each patient. The primary objective of the study is to assess the efficacy of Kent's Repertory in selecting appropriate homoeopathic remedies for the treatment of candidiasis. By analyzing the results obtained through the clinical trial, the study aims to provide evidence for the effectiveness of this approach in controlling Candida infections while minimizing disruption to the body's normal homeostasis.

Recurrent vulvovaginal candidiasis (RVVC) is a long-term condition that significantly impacts the quality of life of affected women. However, global prevalence or lifetime incidence estimates for this disease have not been previously reported. A systematic review was conducted, searching various databases for population-based studies published between 1985 and 2016. The review included eight studies from 11 countries, covering a total of 17,365 patients. The findings revealed that globally, approximately 138 million women are affected by RVVC each year, with a prevalence rate of 3871 per 100,000 women. Over a woman's lifetime, around 372 million are affected by RVVC. The age group of 25-34 years has the highest prevalence rate at 9%. By 2030, the number of women affected by RVVC is estimated to increase to nearly 158 million annually. In high-income countries, the economic burden of lost productivity due to RVVC could reach up to $14.39 billion per year. These results emphasize the significant prevalence, considerable morbidity, and economic impact of RVVC, highlighting the need for improved solutions and better quality of care for affected women. [8]

By addressing the limitations of conventional treatment methods, this study aims to contribute to the development of alternative and potentially more cost-effective approaches for managing candida infections. Ultimately, the goal is to restore the health and well-being of patients suffering from candidiasis, improving their quality of life.

Despite explaining the pathogenesis of the disease, still science fails to explain the difference between two individuals suffering from the same disease. Different individuals manifest disease in different sets of signs and symptoms, which shows us that individuals suffering from the same disease are distinct in their clinical presentation. Therefore, the same medicine cannot be used in different individuals suffering from the same disease.

Homoeopathy as a scientific system of therapeutics is mainly based on individualization and selecting the medicines as per the law of similar, taking into account the totality of symptoms. [4] $153 of the Organon [4] is the homeopathic methodology text that teaches in detail how the process of case taking and case analysis should be carried out. [5]

A man is sick before the localization of the disease. Pathological changes are a part of the totality of symptoms because in some patients pathological changes occur earlier while in others they appear later depending upon the susceptibility of the individual even though suffering from the same disease. In addition, some patients have an inherent tendency as a part of individual characteristic pathological changes peculiar to that individual. Some patients tend to characteristics to suffer from certain
hypertrophy of scar tissue even from minor injuries. [5]

In clinical practice, we often come across cases where patients with the same disease have different individual presentations. While considering the general symptoms of patients, we observe that each individual is unique and differs from others. By taking these characteristic symptoms into account, we can prescribe a homeopathic simillimum and achieve the desired results. It is becoming increasingly evident that every person is unique in terms of their health, and this holds for disease conditions as well. However, there is a lack of detailed literature and research on this topic. Therefore, it is crucial to explore the role of homeopathy in various aspects of the modern presentation of diseases. Repertory is essential in homeopathy for repertorization and to find a group of similar remedies easily and one of the greatest pieces of homeopathic literature left by Dr. J.T Kent is Kent’s repertory of homeopathic materia-matricola. Dr. J.T Kent was one of the most influential homeopaths who had a great impact on the minds of homeopaths of that time as well as new-generation homeopaths. [5]

Complementary and alternative medicine (CAM) treatments have shown promise in managing candidiasis when conventional treatments are not suitable. However, their use is limited due to the lack of clinical trials and large-scale studies providing evidence of their efficacy and safety profile. In the field of homeopathy, a few in vitro trials have been conducted to assess the potential of various homeopathic drugs for treating candidiasis. Nevertheless, further research is needed to establish their usefulness and effectiveness in clinical settings. [3,6]

The objective of this study was to investigate the relevance of general symptoms from Kent’s Repertory contributing to the totality of symptoms and selecting the appropriate homeopathic simillimum for patients with candidiasis. The study involved extracting general symptoms from patients, collecting data, and analyzing them for statistical significance. The aim was to determine the utility of general symptoms in clinical practice and their role in selecting the most suitable homeopathic remedy for candidiasis. [7]

Materials and Methods

Study Setting: The present study was conducted at the National Institute of Homoeopathy (NIH) located in Kolkata, India. The samples for the study were collected from patients attending the Outpatient Department (OPD) of the National Institute of Homoeopathy. The NIH served as the primary setting for data collection and patient recruitment.

Selection of samples: The sample size of 30 patients was determined based on several considerations. As a single-arm, non-randomized, non-controlled clinical trial, the focus of this study was to explore
the effectiveness of individualized homoeopathic medicine in the management of Candidiasis. The primary objective was to evaluate the response to treatment preliminarily.

Given the specific setting of the study at the National Institute of Homoeopathy, the availability of patients diagnosed with Candidiasis within the designated timeframe influenced the sample size. Additionally, practical constraints such as limited resources, time, and the feasibility of conducting the study with the available research team were also considered. Although a larger sample size could have potentially increased the generalizability of the study findings, this preliminary investigation aimed to provide initial insights into the potential effectiveness of the intervention. The inclusion of 30 patients was deemed sufficient for this study, allowing for an initial assessment of treatment response and providing a foundation for future research with larger sample sizes and more robust study designs. It is important to note that the small sample size limits the statistical power and generalizability of the study. Therefore, the results should be interpreted with caution, and further research with larger sample sizes is recommended to strengthen the evidence base for the effectiveness of individualized homeopathic medicine in the management of Candidiasis.

30 (=n) patients fulfilling the inclusion criteria were included in the study.

**Inclusion Criteria**

1. Patient willing to undergo homoeopathic treatment.
2. Patient suffering from any kind of Candida infection without having life-threatening complications.
3. Both sexes, all socio-economic status, all religions.
4. Those patients who have been clinically diagnosed with Candidiasis will be taken for study.

**Exclusion criteria:**

1. Patients not willing to participate in the study.
2. Self-reported immune-compromised state.
3. Cases with Systemic Candidiasis.
4. Severe aggravation.
5. Patient with a history of substance misuse.

**Trial Design:** This is an open-label, prospective, Single-arm, non-randomized, non-controlled clinical trial of pre-post comparison design conducted at the Repertory outpatients department (OPD) of the National Institute of Homoeopathy, Kolkata, India. The study protocol was approved by the Institutional Ethical Committee (IEC) vide 5023/NIH/PG/Ethical comm. 2009/ vol. III/ 1969 (A/S) dated 27.03.2017. The trial protocol (unpublished) and full dissertation were submitted as the postgraduate thesis of the corresponding author to The West Bengal University of Health Sciences.

**Intervention:** Intervention was planned as administration of indicated homeopathic medicines in centesimal and in individualized dosage, as decided appropriate to the case or condition as per cardinal principles of Homoeopathy. Each dose consisted of 6-8 cane sugar globules medicated with a single drop of the indicated medicine, preserved in 90% v/v ethanol. Each dose was directed to be taken orally on a clean tongue with an empty stomach. The duration of such therapy was 3 months. With potency ranging from 30 to 1M as per the susceptibility or demand of the cases. Medicines were obtained from SBL Pvt. Ltd. And Homoeopathy International – GMP-certified firms. Single individualized medicine was prescribed on each occasion taking into account presenting symptoms totality, clinical history details,
constitutional features, and miasmatic expressions. All patients have been prescribed homoeopathic medicine, using Kent’s Repertory after proper repertorization with the help of a repertorization sheet. Subsequent prescriptions were generated as per Kent’s observations and Hering’s law. Medicine was selected on each occasion by two homeopaths by keeping purview on MVHT (Model Validity of Homoeopathic Treatment).

Selection of tools:
The following research tools were used for the smooth conduction interview process.

- Standardized case taking pro forma.
- Repertorization sheet/homoeopathic software [RADAR®, version 10.0.028 (ck), Archibel 2007, Belgium].
- Follow up sheet.
- Numeric rating scales (0-10) showing the severity of mucocutaneous Candidial infection.
- Translated bengali version of the Mucocutaneous Candidiasis assessment questionnaire (MCAQ) for assessment of symptoms of Candidiasis.
- Relevant literature review (books, journals, internet, and other non-book materials). [Done from primary sources (articles from indexed and non-indexed journals), secondary sources (abstracting database services like PubMed, Google Scholar, and IndMed), and tertiary sources (text books).]

Brief of procedures: Different literature dealing with Candidiasis including books related to candidiasis and Kent’s repertory as well as different books of homeopathic materia-medica have been used.

The whole process includes the following steps:

Step 1- Proper case-taking of the patient as per strict homeopathic principles.

Step 2- Analysis and evaluation of symptoms.

Step 3- Relevant investigation done as per need.

Step 4- Measurement of NRS and MCAQ score at baseline.

Step 5- Remedies have been selected based on the totality of symptoms and miasmatical background.

Step 6- Potency, dose, and repetition done after following strict homeopathic principles.

Step 7 - General non-medicinal management which includes appropriate diet, regimen, and proper lifestyle modifications has been given according to the needs and demands of each case.

Step 8- Follow up of the cases as per standard method in homeopathy along with measurement of NRS and MCAQ score after completion of the period of study.

Outcome assessment
Outcome assessment of the treatment was done by considering the improvement of the patient in general and analyzing a scoring scale:

1. **Primary Outcome:** Numeric rating scales (NRS; 0-10) measuring the intensity of symptoms [0: least complaint; 10: worst possible complain].

   - 35% reduction: “minimal relief”
   - 67% reduction: “moderate relief”
   - 70% reduction: “much relief”
   - 94% reduction: “complete relief”

[9] Degrees of improvement are defined a priori as per the below-defined percentage reduction of pain NRS (i.e. the minimally clinically important difference). [10]
2. **Secondary Outcome:**
   Mucocutaneous assessment questionnaire (MCAQ) [11]

**Data collection**

The outcomes were assessed at baseline and after 12 weeks [Table 1]. A specially designed Microsoft MS Office Excel 2007 spreadsheet (master chart) was used for data extraction and was subjected to statistical analysis.

**Statistical techniques & data analysis**

The analysis was carried out with a per protocol approach; i.e. only the protocol-compliant subjects entered into the final analysis. The baseline data descriptive data (categorical and continuous) were presented in terms of absolute values, percentages, means, and standard deviations. A parametric paired t-test was planned to be used as inferential statistics comparing dependent observation of continuous outcomes. P values less than 0.05 were considered statistically significant. No interim and subgroup analyses were planned.

**The methodology for paired t-test**

It is applied to paired data of dependent observations from one sample only when each individual gives a pair of observations (in this study, NRS and MCAQ score before and after treatment). It is used to study the role of a factor or cause when the observations are made before and after its play. The following steps are taken to test the significance of the difference. It starts with the Null hypothesis. It is assumed that there is no real difference between the means of data before and after observations.

**Step 1 Making of hypothesis**

**Null Hypothesis (H₀):** There will be no significant improvement in symptom severity of patients suffering from candidiasis by individualized homoeopathic medicines selected using Kent’s Repertory; i.e., pre-treatment NRS score = post-treatment NRS score or pre-treatment MCAQ score = post-treatment MCAQ score.

**Alternative Hypothesis (H₁):** There will be significant improvement in symptom severity of patients suffering from candidiasis by individualized homoeopathic medicines selected using Kent’s Repertory; i.e., pre-treatment NRS score ≠ post-treatment NRS score or pre-treatment MCAQ score ≠ post-treatment MCAQ score.

**Step 2** fixing the level of significance – the p value is set at 0.05 i.e., 5%.

**Step 3** – calculation

a) Find the difference in each set of paired observations before and after. ($X_1 - X_2 = x$).

b) Calculate the difference of mean ($\bar{x}$)

c) Work out the SD of differences and the SE of mean from the formula:

d) $SE = SD/\sqrt{n}$

e) $SD = \sqrt{\frac{\sum(x - \bar{x})^2}{n-1}}$

f) Determine ‘t’ value by substituting the above values in the formula.

$t = \bar{x}/SE$
Table 1: Showing the baseline and after 12 weeks score for primary outcome (NRS) and secondary outcome (MCAQ)

<table>
<thead>
<tr>
<th>S.No.</th>
<th>NRS score at Baseline</th>
<th>NRS Score After Treatment (12 Weeks)</th>
<th>MCAQ score at baseline</th>
<th>MCAQ score after treatment (12 weeks)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>8</td>
<td>4</td>
<td>13</td>
<td>6</td>
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<tr>
<td>2.</td>
<td>9</td>
<td>3</td>
<td>20</td>
<td>9</td>
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<tr>
<td>3.</td>
<td>8</td>
<td>3</td>
<td>14</td>
<td>4</td>
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<tr>
<td>4.</td>
<td>8</td>
<td>2</td>
<td>18</td>
<td>7</td>
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<td>5.</td>
<td>9</td>
<td>4</td>
<td>18</td>
<td>13</td>
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<tr>
<td>6.</td>
<td>8</td>
<td>3</td>
<td>8</td>
<td>2</td>
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<tr>
<td>7.</td>
<td>8</td>
<td>5</td>
<td>10</td>
<td>4</td>
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<tr>
<td>8.</td>
<td>8</td>
<td>4</td>
<td>19</td>
<td>8</td>
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<tr>
<td>9.</td>
<td>9</td>
<td>6</td>
<td>11</td>
<td>5</td>
</tr>
<tr>
<td>10.</td>
<td>8</td>
<td>4</td>
<td>16</td>
<td>7</td>
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<tr>
<td>11.</td>
<td>7</td>
<td>2</td>
<td>9</td>
<td>2</td>
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<td>12.</td>
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<td>5</td>
<td>9</td>
<td>2</td>
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<td>13.</td>
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<td>4</td>
<td>10</td>
<td>4</td>
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<tr>
<td>14.</td>
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<td>4</td>
<td>15</td>
<td>8</td>
</tr>
<tr>
<td>15.</td>
<td>8</td>
<td>4</td>
<td>15</td>
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<tr>
<td>16.</td>
<td>8</td>
<td>8</td>
<td>16</td>
<td>15</td>
</tr>
<tr>
<td>17.</td>
<td>7</td>
<td>4</td>
<td>14</td>
<td>7</td>
</tr>
<tr>
<td>18.</td>
<td>8</td>
<td>5</td>
<td>16</td>
<td>7</td>
</tr>
<tr>
<td>19.</td>
<td>7</td>
<td>5</td>
<td>6</td>
<td>3</td>
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<td>20.</td>
<td>6</td>
<td>6</td>
<td>12</td>
<td>11</td>
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<tr>
<td>21.</td>
<td>8</td>
<td>5</td>
<td>11</td>
<td>6</td>
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<td>22.</td>
<td>8</td>
<td>3</td>
<td>18</td>
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<td>7</td>
<td>8</td>
<td>19</td>
<td>19</td>
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<td>7</td>
<td>10</td>
<td>7</td>
<td>15</td>
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<td>25.</td>
<td>7</td>
<td>3</td>
<td>14</td>
<td>5</td>
</tr>
<tr>
<td>26.</td>
<td>8</td>
<td>4</td>
<td>8</td>
<td>6</td>
</tr>
<tr>
<td>27.</td>
<td>9</td>
<td>4</td>
<td>17</td>
<td>10</td>
</tr>
<tr>
<td>28.</td>
<td>7</td>
<td>10</td>
<td>12</td>
<td>15</td>
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<tr>
<td>29.</td>
<td>7</td>
<td>3</td>
<td>7</td>
<td>4</td>
</tr>
<tr>
<td>30.</td>
<td>9</td>
<td>3</td>
<td>8</td>
<td>6</td>
</tr>
</tbody>
</table>

g) As per Null hypothesis, there should be no real difference in means of two sets of Observations, i.e., theoretically it should be 0.
a. Find the degree of freedom. Being the same sample, it should be n – 1.

h) Compare the calculated value with the tabulated value (refer to table) at the particular degree of freedom to find out the Probability (P).

i) If the probability (p) is more than 0.05, the difference observed has no significance. But if the P is less than 0.05, the difference observed is significant. If the calculated t-value is greater than the table value at probability (P) of 0.05 then the result is considered to be significant at p ≤ 0.05 and null hypothesis is rejected.

Results

Study flow: As per the pre-specified inclusion and exclusion criteria, 33 patients suffering from Candidiasis were enrolled in the trial. Following that, baseline socio-demographic and outcome data was obtained. After 3 months of intervention, outcome data was recorded again. During the intervention, 3 patients dropped out; 30 completed the trial.

Recruitment: Starting from April 2017, follow-up of the last enrolled patient was completed by the end of June 2018. Each subject was studied for 3 months.
Baseline data: Seven variables were studied for the baseline socio-demographic features of the subjects- age, gender, residence, religion, Residence, Socioeconomic status, Employment status, and type of Candidiasis (Table 2).

Number analyzed: Outcomes from 30 out of 33 subjects were completed and those entered into the final analyses.

Outcome and estimation: Over 3 months of homeopathic treatment, the reduction in NRS [Mean reduction 2.63, 95% CI confidence Interval 4.7 to 7.33, P < 0.05] was statistically significant. Reduction in MCAQ score was also statistically significant over 3 months of homeopathic treatment [mean reduction 5.81, 95% CI Confidence Interval 7.46 to 13.27, P< 0.05]. (Table 2, Figure 1).

Medicine used: In this study, the following medicines were frequently prescribed at baseline:
Sepia (n= 5), Borax (n= 5), Sulphur (n= 4), Natrum Mur (n= 3), Pulsatilla (n= 2) were the most frequently prescribed remedies at baseline. These remedies were administered with potencies ranging from 30 to 1M, based on the susceptibility or demand of the cases. Specifically, 30 potency was prescribed in 8 cases, 200 potency in 18 cases, and 1M potency in 4 cases, as guided by the principles outlined in the Organon of Medicine.

### TABLE 2: Baseline Data

<table>
<thead>
<tr>
<th>Features</th>
<th>N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (yrs; mean ± sd)</td>
<td>27.77 ± 11.37</td>
</tr>
<tr>
<td>Age groups (yrs)</td>
<td></td>
</tr>
<tr>
<td>11-20 years</td>
<td>10 (33.33%)</td>
</tr>
<tr>
<td>21-30 years</td>
<td>14 (46.66%)</td>
</tr>
<tr>
<td>31-40 years</td>
<td>04 (13.33%)</td>
</tr>
<tr>
<td>41-50 years</td>
<td>00</td>
</tr>
<tr>
<td>&gt; 50 years</td>
<td>02 (06.66%)</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>06 (20%)</td>
</tr>
<tr>
<td>Female</td>
<td>24 (80%)</td>
</tr>
<tr>
<td>Residence</td>
<td></td>
</tr>
<tr>
<td>Rural</td>
<td>25 (83%)</td>
</tr>
<tr>
<td>Urban</td>
<td>05 (17%)</td>
</tr>
<tr>
<td>Religion</td>
<td></td>
</tr>
<tr>
<td>Hinduism</td>
<td>14 (44.66%)</td>
</tr>
<tr>
<td>Islam</td>
<td>16 (53.34%)</td>
</tr>
<tr>
<td>Type of candidiasis:</td>
<td></td>
</tr>
<tr>
<td>Vaginal</td>
<td>22 (73%)</td>
</tr>
<tr>
<td>Intertrigo</td>
<td>04 (13%)</td>
</tr>
<tr>
<td>Paronychial</td>
<td>02 (7%)</td>
</tr>
<tr>
<td>Oral thrush</td>
<td>02 (7%)</td>
</tr>
<tr>
<td>Socioeconomic status</td>
<td></td>
</tr>
<tr>
<td>Low</td>
<td>19 (63.33%)</td>
</tr>
<tr>
<td>Medium</td>
<td>11 (36.67%)</td>
</tr>
<tr>
<td>Upper12th</td>
<td>00</td>
</tr>
<tr>
<td>Employment status</td>
<td></td>
</tr>
<tr>
<td>Service</td>
<td>09 (30%)</td>
</tr>
<tr>
<td>Student</td>
<td>02 (7%)</td>
</tr>
<tr>
<td>Dependent</td>
<td>19 (63%)</td>
</tr>
<tr>
<td>Miscellaneous</td>
<td>00</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Outcome assessment parameter</th>
<th>Baseline Mean ± sd</th>
<th>After 3 months Mean ± sd</th>
<th>Mean Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean NRS</td>
<td>7.33 ± 0.83</td>
<td>4.6 ± 2.04</td>
<td>2.63</td>
</tr>
<tr>
<td>Mean MCAQ</td>
<td>13.27 ± 4.18</td>
<td>7.46 ± 4.30</td>
<td>5.81</td>
</tr>
</tbody>
</table>
PEARSON’S CORRELATION BETWEEN GAGS AND CADI SCORE: Pearson’s correlation coefficient showed that there is linear positive correlation between NRS (Numeric Rating Scale) and MCAQ (Muco cutaneous assessment questionnaire) scores. In this study the value of ‘r’ is 0.70 which shows positive correlation between both of two.

Fig. 1: Changes in NRS scores over 3 months

Fig. 2: Changes in MCAQ scores over 3 months

Fig. 3. Pearson correlation between changes in NRS and MCAQ over the period of 3 months.
Inference
The calculated $t_{29}$ value is 8.04 OR 9.17 by using NRS and MCAQ scoring scale and on referring t-table at degree of freedom 29, it is found that the t-value is 2.05 at $p=0.05$. However, our calculated value of 8.04 or 9.17 is $> 2.05$ (t at $p=0.05$). The calculated t-value is greater than the table value at $\alpha = 0.05$. The result is significant at $p \leq 0.05$.

Therefore null hypothesis (Ho) which implies that there is no significant improvement in symptom severity of patients suffering from candidiasis by individualized homoeopathic medicines selected using Kent’s Repertory; i.e. pre-treatment NRS score = post-treatment NRS score is rejected.

Discussion
Principal finding: There were significant reductions in the NRS and MCAQ score after 3 months of treatment with Individualized Homoeopathic medicines selected by using Kent’s repertory in various types of candidiasis cases. Sepia, Borax, Sulphur, and Natrum mur. were the most frequently prescribed medicine. With potency ranging from 30C to 1M in a centesimal scale as guided by principles described in Organon.

Strength of the study: The study is concerned with prescribing individualized homeopathic medicines to patients. We have used standardized outcome scales – NRS and MCAQ, which have made the assessments of outcomes accurate and reliable. The sample size of this study was small, but it was adequately powered to detect changes in the specified outcome measure after 3 months of treatment. The study was taken up as a postgraduate thesis by the corresponding author; therefore, the sample size was small keeping in mind the feasibility issues and stipulated time frame. All the collected data (hard form) was converted into an analyzable and reproducible master chart (soft copy) where all data was extracted systematically and underwent statistical analysis subsequently. We presented the results using sufficient numbers of both tabular forms and pictorials for easy understanding. Enrolment into the study was prospective; i.e. the protocol was drafted and clearance was obtained prior to enrolment of the first patient. The study was transparent in terms of declaration of protocol, ethical conduct and reporting. There was no placebo control and no new drug was experimented on; thus, ethically less vulnerable. There was no violation of routine homeopathic practice and the outcome data was gathered at baseline and after 3 months of treatment. The medicines were prescribed in centesimal potencies. Before enrolment, each patient was provided with a patient information sheet in local vernacular Bengali detailing the study aims and objectives, methods, risks and benefits of participating, and confidentiality issues. After that, written informed consent was obtained. Thus, the study conformed to every possible ethical standard.

Weakness of the study: Follow-up of only 03 months is not sufficient to treat cases of candidiasis as the disease is relapsing in nature. The sample size of this study is too small to make any firm recommendation based on its results. This study did not support conclusions as to either the efficacy or effectiveness of the homeopathic medicines because no methodology for this purpose (control group, randomization, blinding, multi-center study design, etc.) was built into its design. Besides, the trial was open; no blinding was used. Thus patient selection bias, evaluation bias, and data analysis bias might have affected the outcomes of the study. The data may also be helpful in the planning of further research projects on homoeopathy. Validity and reliability of the translated Bengali version of the MCAQ questionnaire remained to be addressed formally in future studies.

Unanswered questions and future researches: Randomized controlled definitive trial using individualized homoeopathic medicines can be up taken
in future with larger sample size and for longer duration of time. Efficacy or effectiveness studies can be planned.

Conclusion

This open-label, prospective, single-arm, non-randomized, non-controlled clinical trial investigated the effectiveness of individualized homeopathic medicine selected using Kent's Repertory in the management of Candidiasis. The study demonstrated promising results, with 86.67% (26 out of 30) of patients showing improvement after the intervention, while 13.33% (4 out of 30) did not show improvement.

The observed 86.67% improvement rate in Candidiasis cases is encouraging, suggesting the potential efficacy of individualized homeopathic treatment in this field. However, it is important to note that this study had limitations, including its small sample size and the absence of a control group or randomization. Therefore, further research with larger sample sizes and more robust research designs, such as randomized controlled trials, is warranted to validate and strengthen these findings.

Significantly decreased Numeric Rating Scale (NRS) and Mucocutaneous Candidiasis Assessment Questionnaire (MCAQ) scores after treatment were observed in the majority of patients. The mean differences between the NRS and MCAQ scores before and after treatment were 2.63 and 5.81, respectively.

In conclusion, the findings of this study suggest that individualized homeopathic medicine selected using Kent's Repertory may be an effective approach for managing Candidiasis. The positive results obtained in this observational study provide a foundation for further investigation. Future studies should incorporate larger sample sizes, rigorous research designs, and appropriate control groups to establish the true efficacy of this treatment approach.

Conflict of interest statement: The authors declare that they have no competing interests. The trial was carried out as the postgraduate thesis of the corresponding author under the guidance of BPS who is a permanent teaching faculty of the institute.

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Authors’ contributions: NKS conceived and designed the study. NKS and RP collected the data. NKS prepared the manuscript. All the authors reviewed and approved the final manuscript.

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