Pilot of a Study to create a valid reliable Olfactory Kit for the South Indian Population: Process and Perspectives

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ABSTRACT

Background: Olfaction is an under-evaluated component of the human senses. This has been changing, especially in the post corona virus disease(COVID-19) era. However, the effectiveness of existing olfactory kits is suspect. There was a felt need to identify commonly recognizable odorants amongst the South Indian population. A questionnaire-based survey was done to avail a "first list" of such substances. The next step was to conduct a pilot study.

Objective: To document the process of a pilot study to create a list of region-specific identifiable odorants, focusing on the rationale, methodology and results thus obtained.

Methods: Based on the questionnaire survey, and considering the feasibility of obtaining raw materials, 16 odorants were decided upon. These were then tested on 37 healthy individuals, of south Indian domicile, over four non-consecutive, arbitrary days, during the working hours of staff, faculty and students of a medical school. The findings were noted down as a simple "Yes / No" based on the accuracy of the answers given by the participants to describe the odorant.

Results: Ripe jackfruit was the most commonly identified smell (34 / 37, 91.9%), followed by Camphor (31/ 37, 83.8%), alcohol-based hand sanitizer (30 / 37, 81%), and coffee (26 / 37, 70.3%). Cow dung was not identified by any of the participants.

Conclusion: A pilot study is often an unavoidable part of a research project. This paper documents its relevance, especially the aspects of feasibility in a larger population, awareness of likely hurdles, and calculation of sample size for the main (community) study.

Keywords: Olfactory Kit, South Indian Population

*See End Note for complete author details

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INTRODUCTION

The testing of olfaction serves as a critical means of diagnosing olfactory dysfunctions, which frequently manifest as the primary clinical indications of neurosensory degenerative disorders. Such disorders may arise from genetic predisposition, trauma, or the onset of old age.[1] There is also the need for documentation of potential olfactory sequelae or complications resulting from various cases of nasal and neurosurgical procedures.[2] This represents an important area requiring more attention in India. The recent recognition of anosmia as a standalone symptom of COVID-19 has further elevated the need for olfaction testing.[3]

A major limitation of such tests, however, is that a number of odors are not universal and, hence, are not familiar to persons in all cultures. Although it would be ideal to have a single universal test, at the present time only tests using a small number of odorants have proved to be universal. Hence, culture-specific adaptations

must be applied to most existing tests to allow for the use of common normative data.[4] Unfortunately, attempts at harmonization are often confounded by small and unrepresentative sample sizes that do not reflect the underlying structure of the populations to which their findings are to be generalized. Hence, the effectiveness of international olfactory kits for evaluating the olfactory abilities of the indigenous population of South India remains uncertain. As a result, it was imperative to develop an olfactory kit that is better suited for South Indian population. The preliminary phase involved the identification of odoriferous compounds that are universally identifiable in South India. This was achieved using a simple questionnaire-based survey among a sample of adult population, administered via Google Forms. The results seemed to validate our hypothesis that some odorants are region-specific (Jasmine and Sandalwood were amongst the top 15). This has been published.[5]

RATIONALE FOR THE PILOT STUDY

The actual validation of the hypothesis can only be after the above selected odorants are tested in the general population, two key questions had to be answered first. Firstly, was a mere questionnaire survey sufficient, and valid, for a physical function such as olfaction? Secondly, how many individuals needed to be tested in the community? To address these pertinent questions, the only option was to conduct a pilot study.

A suitable definition of a Pilot study goes thus: "a small study conducted in advance of a planned project, specifically to test aspects of the research design (such as stimulus material) and to allow necessary adjustment before final commitment to the design.[6] There is no doubt that a pilot is an important, and often inevitable, part of a clinical research study. However, it often goes unreported, or is simply included as an addendum in the main study publication. This neglect has been highlighted in an earlier article.[7]

Table 1. List of the odoriferous substances used	
1	Ripe Jackfruit (individual fleshy pods)
2	Camphor
3	Alcohol Based Sanitizer
4	Coffee
5	Naphthalene
6	Jasmine
7	Garlic
8	Cinnamon
9	Asafoetida
10	Sandalwood
11	Clove
12	Lemon
13	Cardamom
14	Rose
15	Nutmeg
16	Cow dung

The study protocol was presented to the institutional ethics committee, and approval was obtained. (ECASM-AIMS-2023-285)

Hence, the present article is intended as a description of the process of a pilot study done as part of the quest to identify region-specific identifiable odorants, focusing on the rationale, methodology and results thus obtained.

MATERIALS & METHODS

Based on the questionnaire survey, and considering the feasibility of obtaining raw materials, 16 odorants were decided upon. These are listed below **(Table 1).**

These were either freshly cut raw substances (fruits, vegetables, spices and herbs) or bottled fragrant

Figure 1. Sealed labelled containers with the odoriferous substances chosen for testing

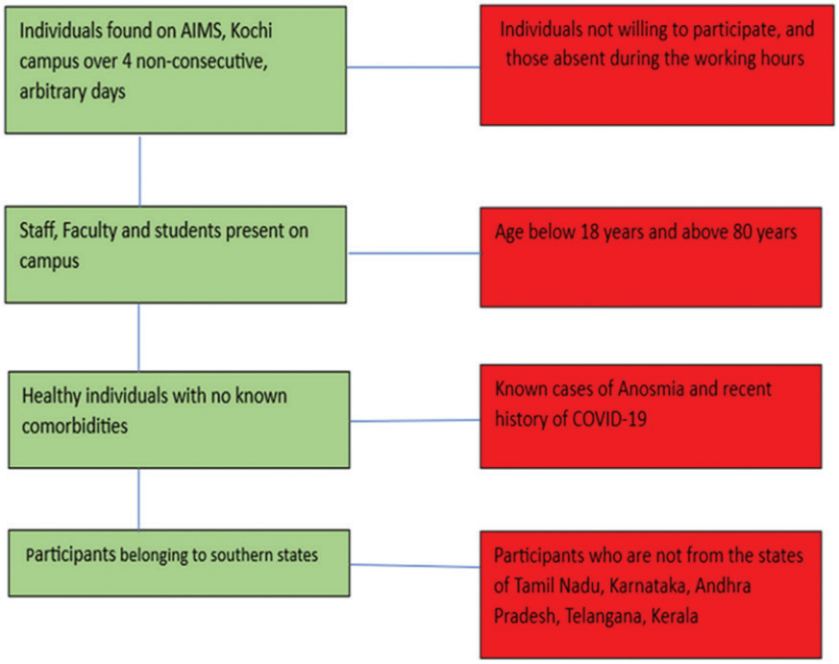

Figure 2. Depicting the selection of participants for the Pilot

essential oils dispersed on circular cotton pads just prior to testing. All these were stored in small, plastic, cylindrical containers, tightly closed to prevent loss of aroma **(Figure 1).**

We conducted the survey on 37 individuals in the campus of Amrita Institute of Medical Sciences, Kochi over four nonconsecutive, arbitrary days, during the working hours of staff, faculty and students. The subjects were individuals present on the campus with no prior complaints of loss of smell and no recent history of COVID-19 infection. Their domicile status was checked first, so as to include those from the five South Indian states viz. Kerala, Tamil Nadu, Karnataka, Andhra Pradesh, Telangana. The name, age, sex and occupation of the participants were documented. Age range for the study was fixed at 18 to 80. The findings were noted down by either one of the three principal investigators of the study, as a simple "Yes / No" based on the accuracy of the answers given by the participants to describe the odorant. The selection process is depicted in **Figure 2.**

Each participant was first briefly explained about the goal of the study and verbal consent was taken. The participants were seated away from the line of sight of the labelled samples, so as to prevent guessing. They were requested to keep their eyes tightly shut, and the samples were placed in close proximity to both the nostrils, the container resting against their philtrum. They were given 10 seconds to smell the samples, one at a time, and were requested to identify the substance from the smell. Answers that were descriptions of the food that the raw substances were predominant in, such as "biriyani" for a sample of cinnamon, only indicated that the smell was familiar to the participant through the food substance, but not a distinct individual odorant. This was marked as a "No". Responses that included accurate descriptions of the individual odorant itself, such as describing cinnamon as a "brown, long, cylindrical, bark-like spice" due to the participant's inability to recollect the name of the substance, or due to inability to translate the name of the substance from their native language to English, were counted as valid answers ("Yes"). The number of participants chosen for this survey was at random(convenient sampling), as it was dependent entirely on the primary investigators' ability to scout for individuals available on the feasible days, during the working hours, and willing to participate in the

Table 2. Participants able to identify the odorants accurately (n=37)

	Odoriferous substances	n(%)
1.	Ripe Jackfruit	34(91.9)
2.	Camphor	31(83.8)
3.	Alcohol based sanitizer	30(81.1)
4.	Coffee	26(70.1)
5.	Naphthalene	25(67.6)
6.	Jasmine	25(67.6)
7.	Garlic	24(64.9)
8.	Cinnamon	24(64.9)
9.	Asafoetida	22(59.5)
10.	Sandalwood	21(56.8)
11.	Clove	20(54.1)
12.	Lemon	20(54.1)
13.	Cardamom	18(48.6)
14.	Rose	16(43.2)
15.	Nutmeg	08(21.6)
16.	Cowdung	0(00)

study, and fitting the inclusion criteria of domicile and age. It was of interest to the investigators to note the refusal to participate by one individual, citing possible contamination by the previously tested person/s.

Statistical methods: Data were entered into Excel and analyzed.

RESULTS

A total of 37 people was tested for identification of 16 odorants used.

Ripe jackfruit was the most commonly identified smell, as 34 out of the 37 (91.89%) participants were able to accurately identify the sample. The second most commonly identified smell was of camphor, 31 out of 37(83.78%), followed by alcohol-based hand sanitiser, 30 out of 37(81.08%). Coffee was identified by 26 out of the 37(70.27%) participants. Cow dung was not identified by any of the participants. The results are as shown in **Table 2**.

DISCUSSION

Ripe jackfruit was the most commonly identified smell, getting 34 out of 37 (91.9%) correct responses. This can be explained by both its provenance and its strong smell. Jackfruit is believed to be from South India and dates back over 5000 years. It has been described as smelling variously like bubble gum, pineapple, banana, and rotten onions.[8] Another study has detailed the compounds that are responsible for its typical smell.[9] This odorant leading the list itself validates the contention that a region-specific olfaction kit is indicated. However, a point against its feasibility in a kit is its seasonal nature, and need to be used fresh. For the present study, the investigators had to ensure availability of fresh pods on the morning of the test day.

Camphor, with its strong fragrance, is a well-known item in Hindu religious functions, and as aroma oil in beauty and food industry. This familiarity amongst the tested population is probably the reason that it was the second most commonly identified odorant. Its feasibility for use in a kit is quite good.

The alcohol-based sanitizer scoring high was somewhat of a surprise. This could be the effect of heightened awareness in the post-COVID era. There is an interesting online article about the gradual change in smell of commonly available hand sanitizers over the two years, 2020-22.[10] This recognizability may change in the future, and so may not necessarily be recommended as an olfaction kit component.

Coffee was in fourth place with only 26 out of 37 (70.3%) identifying correctly. This has indeed been intriguing, considering that it had scored second on our questionnaire list. It also varies from many international studies where coffee is acknowledged as the most recognizable odorant around the world.[11]

The complete non-identification of cow dung could be explained either due to loss of hydrogen sulphide and ammonia from cow manure from the time of collection to time of testing,[12] or the non-rural background of tested participants.

Our prior online survey managed to effectively utilize a self-designed questionnaire via Google Form, disseminated amongst a cross-section of the South Indian community. Its results showed Jasmine and Coffee as the two most commonly identified odorants. It is interesting to note their altered status, showing the difference between theoretical and practical testing. Another aspect acquired from this pilot study has been the need to address participant concerns about the sanitary measures to be followed while performing the tests in the community. This deviation further strengthens the argument for a personalized olfactory assessment kit that caters to the distinct needs of the South Indian population. It can be extrapolated that there is also a need to develop region-wise customization of olfaction testing kits for clinical use. The results of this study indicate the need to expand the survey to a larger South Indian population, that could lead to the creation of a definitive olfactory kit for this population.

CONCLUSIONS

The present pilot study has clarified the likely odorants that can be considered for the composition of an olfaction kit specific to the South Indian population. The conduct of the pilot study has shown its feasibility in a larger population, along with an awareness of the likely hurdles. Lastly, it has helped in calculating a sample size for the main (community) study.

Future plan

To conduct the study, with the odorants used in this study, in the wider population, either at home or in a peripheral healthcare setting, so as to complete the process of identification of reliable and feasible odorants for use in an olfaction kit in Kerala, and conceivably, South India.

END NOTE

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