AROMATHERAPY
INTANGIBLES

Blinded, placebo-controlled clinical trial to evaluate the “intangible” benefits of aromatherapy on human health.

FRANKLIN
SCHOOL OF INTEGRATIVE
HEALTH SCIENCES

The Alliance of International Aromatherapists is a proud
The Study

Actions of essential oils often utilize standard medical terminology, such as expectorant or antifungal. More commonly, however, aromatherapy benefits do not follow medical norms. Many essential oils are known through experiential use to be grounding, invigorating, calming, or uplifting. These effects have long been considered to be intangible—factors which are unable to be measured, thus unable to be scientifically substantiated. However, psychological measurement tools have been developed which are able to measure mood states related to these effects. These measurement tools have been analyzed to confirm sufficient validity and reliability for clinical research into these effects.

Aromatherapy

This study identifies and measures these “intangible” benefits of essential oils among adults females who experience aromatherapy inhalation through the use of multiple validated psychological measurement tools.

The study will have 4 arms allowing for the comparison of 3 different essential oils and a control group. Each arm will be reflected in 3 groups tested on different days to control for the potential of season or weather to affect mood state.

Participants will complete four different validated measurement tools. This will enable the research team to not only evaluate total effects on intangible benefits but also specifics regarding the way in which these effects are achieved. This will produce multiple outcomes for analysis that enable a comprehensive review of the total effects of aromatherapy.
THE CLINICAL TRIAL

Phase 1 Randomized Controlled Trial (RCT)

Study At-A-Glance
This study identifies and measures the effects of single-oil aromatherapy exposure on outcomes often considered to be intangible among otherwise healthy adults during the study period. Outcomes are related to mood states, subjective wellbeing, overall wellness, and mental/cognitive state.

Outcomes
This study will evaluate 17 outcomes which have been linked to aromatherapy inhalation. These include: Tension, Anxiety, Anger, Hostility, Fatigue, Inertia, Depression, Dejection, Confusion, Bewilderment, Coping Potential, Overall Satisfaction with Life, Sense of Personal Safety, Optimism of Future Security, Connectedness, Achievement, and Subjective Wellbeing (Happiness). These effects are measured through validated research instruments which will enable a comprehensive and robust analysis of not only total effects, but specificity regarding the method by which the effects are achieved.

Size
To achieve the power (80%) and significance (95%) required to avoid type 1 and type 2 errors for each of the outcomes, with a medium minimum effect size of interest ($F = .25$), this study will require 128 adult female participants. This is the total number of subjects determined by preliminary statistical analyses to reduce the risk of false positives and false negatives. The FSIHS research team will not conduct underpowered or overpowered studies as those are unlikely to produce findings which are both statistically and practically significant.

Cost

<table>
<thead>
<tr>
<th></th>
<th>Cost</th>
<th>Timeframe</th>
</tr>
</thead>
<tbody>
<tr>
<td>Startup</td>
<td>$8,125</td>
<td>Start of Study</td>
</tr>
<tr>
<td>Intervention</td>
<td>$12,525</td>
<td>September - November, 2019</td>
</tr>
<tr>
<td>Completion</td>
<td>$4,475</td>
<td>December, 2019</td>
</tr>
<tr>
<td>TOTAL</td>
<td>$25,125</td>
<td></td>
</tr>
</tbody>
</table>

Note: Timeframe listed is based on estimates of study recruitment and completion on the following page.
TIMELINE

From Startup to Results

Overall Time Requirements
This study requires ample time to recruit qualified participants, administer the intervention, maintain quality control, and properly analyze the data. This is estimated to take approximately 7 months in total.

Timeframe
Assuming that the study follows a typical timeline, the study could be complete as early as December, 2019. Note that the estimated completion dates are based on funding availability. Delays in funding lengthen the timeframe.

Estimated completion dates are as follows:
June 2019: Protocol Development
July - August 2019: Project Funding
September 2019: Obtaining Ethical Authorization, Trial Registration,
Late September - October 2019: Recruitment and Implementation of Intervention
November 2019: Data Processing, Analysis, and Compilation of Results
December 2019: Presentation and Dissemination of Results

Factors Influencing Timeframes
Timelines are estimates and are not guaranteed. In the unlikely event that a participant in a study experiences a serious adverse event, the study may be halted to file the required reports with the ethical boards and to obtain authorization to continue the research. Total time to completion can also be affected by unrelated factors which influence participant recruitment and data analysis.
EXPLANATION OF COSTS

Startup Costs

- Regulatory authorizations, and fees including but not limited to: IRB authorization from an accredited ethical review board, registration of the clinical trial with a WHO approved registry, and preparation/submission of related regulatory documents and fees.
- Development of research methodology, including data analysis strategy and protocols to address unforeseen events such as injuries to subjects.
- Preparation of research site and training for personnel involved in the collection of data, including confirmation of human research participant training with updates as needed.

Intervention Costs

- Advertising for participant recruitment to achieve a random sample, participant risk/benefit disclosure(s), screening volunteers for eligibility, subject randomization, administering the intervention, subject debriefing, and participant compensation.
- Monitoring of subjects for adverse events and reporting of any events to ethical oversight agencies and other required authorities.
- Licenses required to reproduce and administer copyrighted validated measurements.
- Archival and secure storage of all data, as mandated by federal law, and management of any random audit from the regulatory agencies that oversee research on human subjects.
- Pre- and post-test data collection, secure data entry, data cleaning, analysis using suitable statistical software packages with required licenses, and secure data management.

Finalization & Dissemination

- Filing of completion records and associated fees with ethical oversight agencies, and updates to registrations in clinical trial registries.
- Presentation of research findings to the sponsor, along with a completed manuscript, using the appropriate industry-accepted formats such as CONSORT or PRISMA.
- Publication costs and APCs (author publishing charges) related to dissemination of the findings. (Studies with multiple outcomes or complex analysis may produce multiple manuscripts, findings, or articles.)

Note: If the study produces noteworthy results, whether positive or negative, the FSIHS Research Team reserves the right to present these findings at industry conferences or disseminate them through other methods, including submissions to scientific journals. Scientific ethics prohibit funding agencies from influencing decisions regarding the dissemination of findings.