

Shagun Goyal

Supervisor – Dr. Simon Poon

School of Information Technologies

FACULTY OF ENGINEERING & INFORMATION TECHNOLOGIES

1) INTRODUCTION

Comparative Effectiveness Research (CER) is a research methodology that emerged in 2009 in the United States. CER aims to generate evidence about the effectiveness, benefits and harms of a particular intervention in comparison with the alternative therapies available for treating a particular ailment.

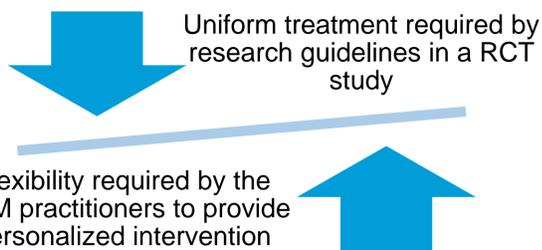
Traditional Chinese Medicine (TCM) is steadily growing in popularity worldwide. But this complementary medicine system can only gain acceptance in the health-care policies of western countries if the evidence for the effectiveness of TCM remedies is rigorously established.

By using the novel CER procedures, evidence regarding the effectiveness of different TCM interventions can be gathered.

3) PROBLEM DESCRIPTION

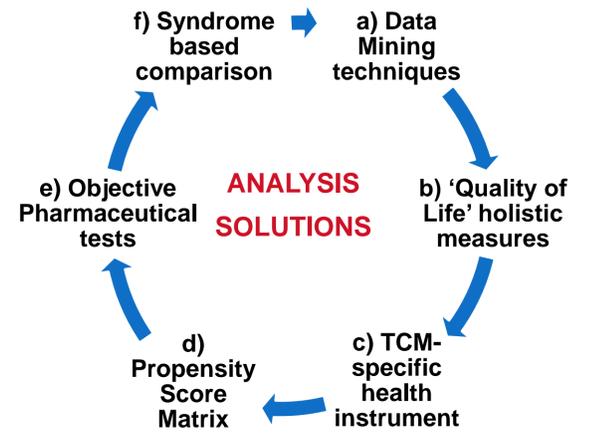
The conventional RCT procedure is not suitable for evaluating TCM. This is because TCM follows the 'patient-centered research' paradigm which involves varying the treatment provision based on the unique characteristics of an individual patient. This approach is inconsistent with the 'evidence-based research' paradigm of RCT which involves assessing the average effects of a homogeneous treatment provided to a group of participants.

To resolve this conflict, innovative augmentations to the RCT methodology are required that will enable accurate evaluation of TCM remedies.



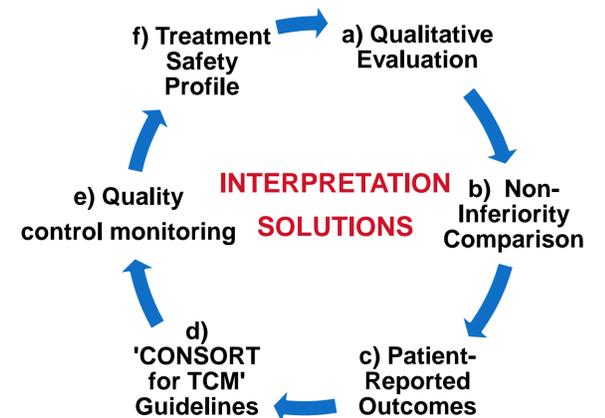
ANALYSIS

Augmentations to the 'analysis' phase of a RCT includes variations made to the manner in which outcomes of the clinical study are measured and assessed.



INTERPRETATION

Augmentations to the 'interpretation' phase of a RCT study includes variations made to the manner in which the results of the clinical study are evaluated and published.

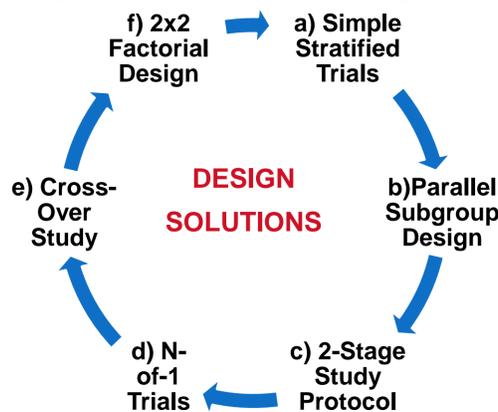


4) SOLUTION GENERATION

A meticulous literature search across 5 key Health Informatics databases was conducted to find innovative augmentations to the RCT methodology. These 5 databases were: AMED (Allied and Complementary Medicine), PubMed, ScienceDirect, Web of Science, and Chinese Journal of Integrative Medicine. The solutions are classified according to the four phases of a RCT study – DESIGN, CONDUCT, ANALYSIS, INTERPRETATION.

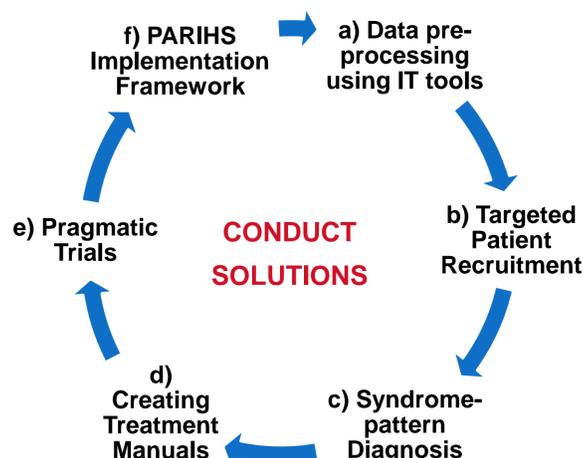
DESIGN

Augmentations to the 'design' phase of a RCT includes variations to the manner in which patients are selected into the trial or altering the timing of treatment provision during the study.



CONDUCT

Augmentations to the 'conduct' phase of a RCT includes variations in clinical trial management and the way in which treatment is delivered to the patients.



5) SOLUTION EVALUATION

A comparison matrix was used for deriving a feasible sub-set of solutions. In a pilot interview, the six solutions for each phase of the RCT methodology were examined using the following criteria. The relative weightings given to each criteria are shown in brackets.

- Cost of Implementing the RCT (17%)
- Time needed for Implementing the RCT (17%)
- Impact on RCT Management and Logistics (15%)
- Impact on Internal Validity of the RCT (30%)
- Impact on External Validity of the RCT (21%)

The summary results from the pilot interview are presented in the colour-coded matrix below.

SOLUTION	A	B	C	D	E	F
DESIGN	Green	Yellow	Yellow	Red	Red	Green
CONDUCT	Green	Yellow	Yellow	Red	Red	Green
ANALYSIS	Green	Yellow	Yellow	Red	Red	Green
INTERPRETATION	Yellow	Red	Red	Green	Green	Yellow

6) CONCLUSION

If the design, conduct, analysis and interpretation phases of RCT studies are tailored, then the clinical trials will become more accommodative of the distinct TCM philosophy.

The results from this study will develop a new instrument for CER that can be used to accurately evaluate alternative therapies such as TCM. The evidence generated will result in far-reaching acceptance of TCM amongst the general population, medical community, and by the governments world-wide.

Finding Evidence using CER

Conduct a Systematic Review using the existing research studies like clinical trials, observational studies etc.

Carry-out new research studies that can be either:

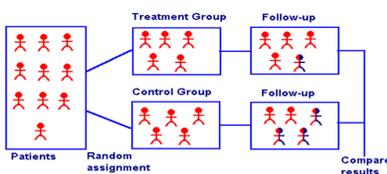
- RCT with an augmented methodology (**my focus**)
- Observation studies using Electronic Health Records, Insurance Claims data etc.

2) BACKGROUND CONCEPTS

There are 3 fundamental concepts that formed basis of my research: RCT, TCM, and Difference between TCM and Western Medicine (WM).

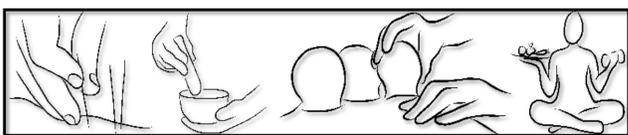
Randomised Controlled Trials (RCT)

The following diagram (Source – *Suny Downstate Medical Center*) demonstrates the procedure of carrying a RCT study.



Traditional Chinese Medicine (TCM)

This diagram (Source – *healthinflow.com.au*) shows the key components of TCM. These components are acupuncture, Chinese herbal compounds, cupping, acupressure and diet therapy.



Difference between TCM and WM

	TCM	WM
Diagnosis	Tongue diagnosis, pulse diagnosis, looking, smelling, asking	Standardized and Straightforward procedure for each patient
Treatment Provision	Personalized treatment provision to each patient	'One-size-fit's all' – similar treatment to all patients
Treatment Focus	Restoring the flow of 'Q' in the entire body	Curing the specific disease, reducing the symptoms