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# THURSDAY AFTERNOON IN CLINIC

Why complementary therapies are truly complex interventions, and a possible strategy for interventional research

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# PhD: Sessions of Acupuncture and Nutritional Therapy Evaluation for Atrial Fibrillation (Santé-AF)

- NIHR Clinical Research Network / York Trials Unit, funded by the British Acupuncture Council and the CRN, ISRCTN13671984 [1]
- Feasibility study – acceptability, recruitment, retention, etc
- Methodological feasibility of using RCT to investigate “truly” complex interventions



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**Santé-AF** Sessions of Acupuncture and Nutritional  
Therapy Evaluation for Atrial Fibrillation

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Feasibility study to inform a randomised controlled trial

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# NIHR Health Technology Assessment on complex interventions

- Updated in 2021 [2]
- “Best-yet” framework for investigating complex interventions
- But still based in reductionist scientific method
  - No methods recommended suitable for investigating Traditional, Complementary and Integrative Medicine in a fully representative way

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## Health Technology Assessment

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### Framework for the development and evaluation of complex interventions: gap analysis, workshop and consultation-informed update

Kathryn Skivington, Lynsay Matthews, Sharon Anne Simpson, Peter Craig, Janis Baird, Jane M Blazeby, Kathleen Anne Boyd, Neil Craig, David P French, Emma McIntosh, Mark Petticrew, Jo Rycroft-Malone, Martin White and Laurence Moore

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## Complementary therapies and holism

- Acupuncture and nutritional therapy (NT): holistic conception of health [3,4]
- Holism: understanding the world as comprising inter-related entities that can't be understood by investigating the entity's constituent parts individually [6]
- Affinity with complexity science and complex adaptive systems [5]



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“In health research, complexity science involves... collecting data from across physical body systems and wider biopsychosocial systems... designing complex interventions composed of multiple interlocking modalities that take all the data into account... measuring emergent and qualitative outcomes, and... responding to feedback loops that allow adaptation, over and over again, of the intervention to the participant. Acupuncturists just call that *Thursday afternoon in clinic.*” [7]





## Holism versus reductionism (TCIM versus biomedicine)

- Reductionism: all entities are made up of constituent elements; break down the entity into its elements = understand (investigate, treat) the whole [8]
- Biomedicine (reductionist model) sees the patient as a collection of different elements, and isolates, investigates, treats the elements independently [9,10]
- Complementary medicine (holistic model) sees individual elements as interconnected with the unique whole of the patient, and treats the patient as a whole [11]
- Reductionism underpins not just biomedicine but the scientific method used to investigate it [12]



## Reductionism as investigatory method for TCIM

- If TCIM treatments are holistic and individualised, how can it be investigated using a reductionist method?
- 2021 NIHR complex interventions guidance still based on reductionist methods – specifically the RCT



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## Pragmatic trials to investigate TCIM

- Pragmatic trials mirror “real world” interventions – practitioners can work as they usually do [13,14]
- But even a pragmatic trial is still a trial – results are focused at group level
- Gives judgement on general effectiveness but doesn’t capture individually meaningful effects for unique patients
- We need ways to investigate both – pairing reductionism with holism in new methodologies showing results at group and individual level



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# Extending the RCT

- Case reports or case series focused at individual patient level and nested in pragmatic RCTs combine:
  - Strength of reductionism (narrow focus, well-defined variables)
  - Strength of holism (detailed representation of intervention's range of effects for individual patients in specific contexts)
- Case study methodology adds value:
  - Nuances overall trial findings
  - Adds value and real-world generalisability to trial findings [15]
  - Suggests additional contexts where intervention could work [16]
  - Trial results become informative for practitioners [17]
  - Opportunities for practitioners to be directly involved in research [18]



## Next steps

- Model for integrating the two methodologies
  - Strategies for selecting cases within trial cohorts
  - Methods for nominating and describing “features of interest”
  - Appropriate points for integration/adjustment of trial interventions
  - Methods of data capture that don’t overburden the practitioner (clinical audit taken from notes?)
- Pilot trials of trials (!) along with process evaluations
- Feedback and integration with clinical trials colleagues





# Thank you

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