Study design for Biodanza and 'body-work therapies'

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(with acknowledgements to Marcus Stueck)

The problem

Naive Biodanza study

- Look at effect of a series of classes.
- At the end, the students score a little better (on e.g. wellbeing)
- Conclusions: ???
  - 1. Biodanza works and is good for everyone;
  - the whole world should do Biodanza (Rolando Toro said so)

- Problems:
  - 1. would any other class have been as affective?
  - 2. Is the result repeatable? (or just by chance?)
  - 3. It was only good for those in that class. How did they get there?
    - Where they typical of the whole world's population?
  - 4. How do you show (objectively, scientifically) 'Biodanza works'?

Consensus paper

Estimating Kinetic Parameters From Dynamic Contrast-Enhanced T_1-Weighted MRI of a Diffusable Tracer: Standardized Quantities and Symbols

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1. Invite all researchers in the field to contribute and be co-authors
2. Define new international standards of methodology and reporting
3. All authors then have to conform to these in their own work
4. Precedent: MRI consensus paper had 800 citations and was in top 25 papers in lifetime of journal

Clinical trial as a paradigm

- In clinical medicine, drug trials have an established study design which measures objectively whether a drug intervention has had an effect.
- This paradigm can give us inspiration on how to design studies on the effects of Biodanza and body work in general.

Double-blind randomised controlled trial

1. *Sample size* (statistical power depends on effect size and variance within groups)
2. one or more *control groups*; the treated group is compared to the control groups.
   - The control groups could be placebo or another established treatment
3. The allocation of patients to the groups should be *random*
   - (otherwise if a group difference in outcomes is found, it is unclear whether this derives from a difference in the group patients at the start of the study (e.g. motivation), or from the treatment under test).
4. various *outcome* measurements (can be clinical, radiological or immunological).
5. patients should be *blinded* to which treatment they are receiving
   - (otherwise they could respond positively to a treatment that they favour, via a psychological/pathological/immunological coupling mechanism).
6. doctor (therapist) should be *blinded* to which treatment they are giving (otherwise they might unintentionally favour the treated group over the control group).
7. The outcome variables can be measured at *different time-points* after treatment
   - (e.g. a *survival curve* shows the proportion of patients surviving (still alive) as a function of years after treatment; compare to the curve for untreated patients).
8. *Patient selection*, taking into account specific treatment effects that are expected, often allows a positive result to be found in a smaller study

Practical difficulties

1. *Patient blinding* is often ineffective because the treatment may have obvious side-effects, whilst a placebo control does not. Some treatments physically are obvious (e.g. physiotherapy).

2. *Patient retention* can be poor; patients *drop out* of long studies because of side effects or the effort of staying in the study. Drop outs introduce a selection bias, since those who drop out are not chosen at random, and the group remaining has different properties from what it had at the start of the study.

3. *Statistical power* is often insufficient to see small effects. The sample size may be too low, there may be too much variance in each group (i.e. they are not homogenous, but respond differently to the treatment), or the outcome measures may be unreliable (again introducing confounding variance).

Data analysis

1. If *too many outcome variables* are analysed, then some may appear to be significantly altered, just by chance.
   - it can be tempting to only report the variables that pass the t-test.

2. Bonferoni correction is needed; this reduces the sensitivity of the study,
   - real effects can be missed.

3. A 'fishing expedition' (investigating many variables) can be useful in identifying outcome variables that might be relevant in a future study.

4. A second approach is to decide, in advance of the analysis, on a *small of number of variables* which will be analysed
   - then the power is not reduced by a Bonferoni correction

Biodanza studies

1. Forced away from the double blinded randomised control trial design, principally because blinding is impossible (for both therapist and subject).

2. In addition, subjects may not be randomly allocated to groups, so there is a bias in those who chose particular treatment groups.

3. Nevertheless, academic studies in areas such as CBT (Cognitive Based Therapy), physiotherapy and Well-being have produced results which are respected.

4. In the UK, CBT is now funded by the state (National Health Service),

5. CBT story may give us a model for how to demonstrate objectively to state funded bodies the efficacy of 'treatments' such as Biodanza.

Areas needing attention
(in meta analysis or new study)

- Intervention (treatment) design.

  Biodanza teacher, group size, duration, intensity, emphasis, intention

  (a Biodanza class varies more than a pill!)
- Choice of subjects –

  can be random or specifically those expected to benefit from the treatment mechanism.
- Choice of control groups

  (which of the effects of Biodanza are you trying to control for? e.g. the physical exercise aspect?)
- Matching of control groups –

  is the amount of therapist intervention similar in all groups?
- Allocation to groups – **ideally should be randomised**;
  - if not, then subjects have to be carefully characterised, including motivation.
- Maximising retention, particularly in a long study
  - Why do some leave?

Areas 2: outcome variables

- Identification of outcome variables. Outcomes can be psychological instruments (stress, well-being, emotion recognition etc), or biochemical (from saliva or blood).
- Align Biodanza class intentions with outcome variables, for maximum effect
  - Biodanza: Vitality Sexuality Creativity Affectivity Transcendence
  - Cecilia: the Chilean Bolivian experience
- Measurement time-points: report values before study, immediately after treatment and long-term effect ('stabilisation').
- Maybe also effects during the intervention. (short-term)

Areas 3: analysis

- Analysis, including confounding variables and Bonferoni correction.
- Give effect size and confidence limits.
- Objectivity, regardless of emotional attachment to one treatment.
  - In an unrandomised study:

  " the Biodanza group improved, therefore Rolando Toro is God"
  - Speaking as Academic or Religious follower??

Italian study Giannelli et al. 2015

- 9 month-long Biodanza course
- 255 people were in three groups:
  - Biodanza
  - Physical exercise (principally Latin-American dance, also gym),
  - Sedentary
- Allocation to groups seemed to be by the participants' choice (i.e. the study was not randomised).
- Unclear how much therapy the other two groups received
- The Biodanza group did show a large improvement in various well-being scores (as the study organisers had hoped!)
- Detailed analyses showed that the Biodanzers started the study with lower well-being scores, and at the end had improved to reach the values of the other groups; in contrast the other groups showed little change.

Italian study - 2

- The authors concluded that "The results support the hypothesis that Biodanza ... promotes health, inasmuch as those who participate ... demonstrate an increase of well-being and a decrease in stress and Alexithymia"

  'Alexithymia' = emotional dysregulation

- This rather general statement is not justified. It blurs the distinction between those who choose to complete the Biodanza, and the general population.
  - Retention rate 58%

- All that can be said is "in those who chose to do Biodanza for a 9 months, there were improvements in well-being".

Are Biodanzers different?

- The possibility that people who volunteer for Biodanza have lower well-being than 'normals' is intriguing.

  Also 'personal growth' higher than sedentary group
- importance of randomised allocation to treatment groups, and of including such variables in the study design.
- The drop-out rate in this study was high

  (only 58% of subjects stayed to the end of the course)

  perhaps 'motivation' should be included as a (confounding) variable

  More attention should be given to retaining subjects.
- Those who volunteered for Biodanza and remained might have high motivation to improve their own well-being and happiness (compared to the subjects in the other groups).
- may explain the phenomenon where subjects who are enthusiastic about Biodanza then recommend it to their friends who find it does nothing for them.
- benefits of Biodanza are only available to some people, and cannot be seen as something which the whole population could benefit from.

Future studies

- ? first identify people with the kinds of low wellbeing found in the Biodanzers
  - then randomly allocate them to several groups
- analogue of patient selection manoeuvre in clinical studies
  - improves sensitivity (increased effect size)
- Children study by Marcus Stueck
  - those with lowest cores benefitted most.
- Match class design and subjects to desired effect
- Better and standardised study design gives:
  - Bigger treatment effect
  - more publishable positive results
  - believed by funding bodies