

# Long term follow-up in Randomised Trials with Delayed Intervention for the Control Group

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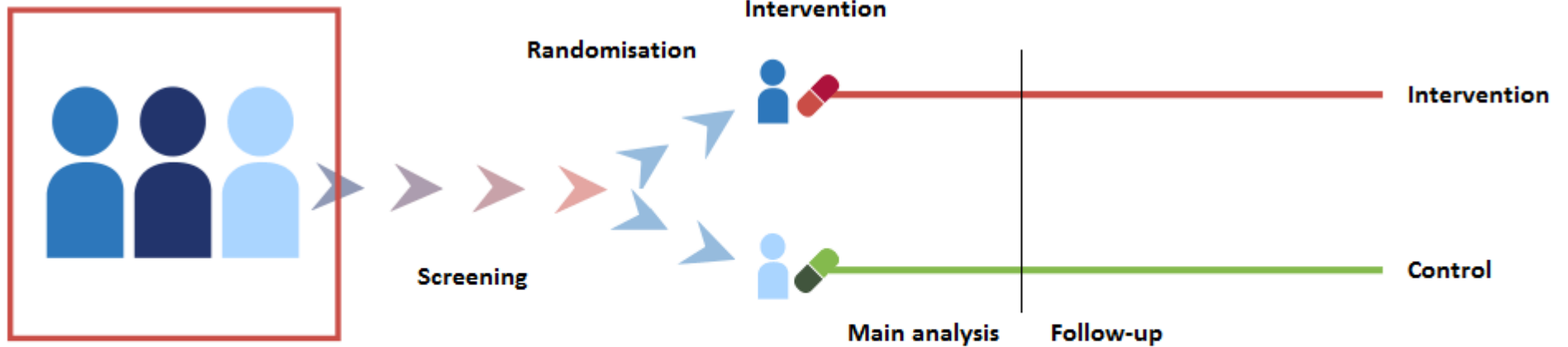
<sup>2</sup> University of Edinburgh

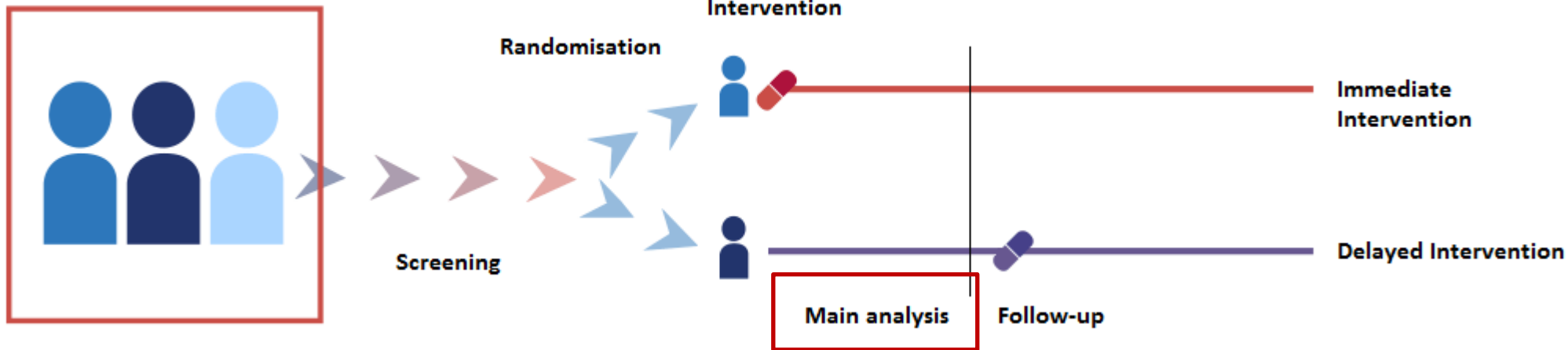




## Gold Standard

Randomised controlled trial





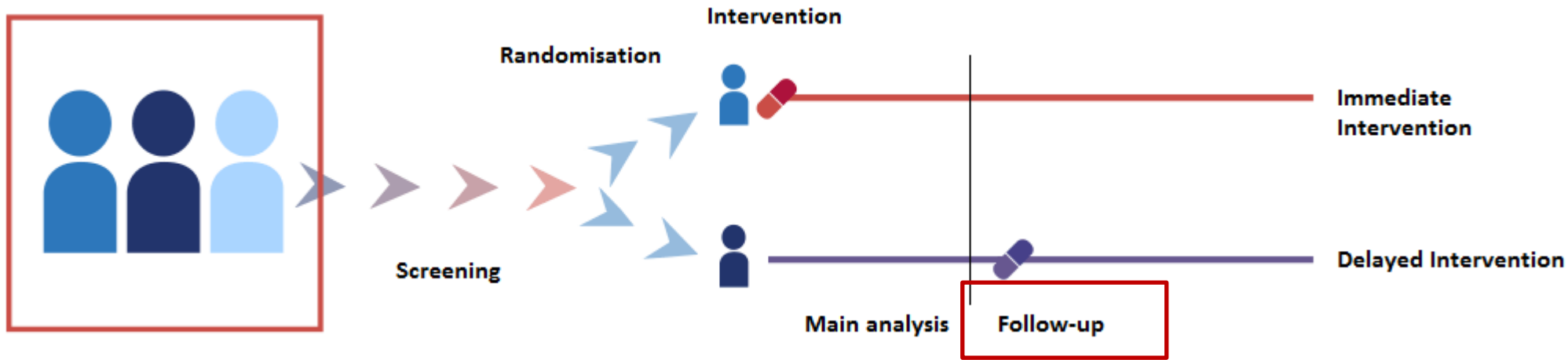
## Delayed Intervention (Wait-list) Control Design

- Control group wait for the active treatment
  - Still under standard care
  - Often receive the intervention after primary outcome data collection
- Main analysis = a randomised comparison
  - Uses data collected prior to the control group receiving the intervention



## Delayed Intervention Control Design

- Not without issues
  - Length of waitlist
  - Increased motivation in delayed group
  - Experience gained during initial delivery effect delayed delivery
- Widely used in RCTs of behavioural interventions
  - Exercise programmes, psychological therapies
  - Where randomised, placebo controlled trials is not possible
  - Investigating mode of delivery
    - Intervention generally beneficial
    - most want to receive the intervention
  - Ethical advantages



## Follow-Up of Delayed Intervention Controls

- Additional information can be obtained by collecting data after control group received the intervention
  - Intervention effect in the delayed-intervention group
  - Maintenance of behavioural changes

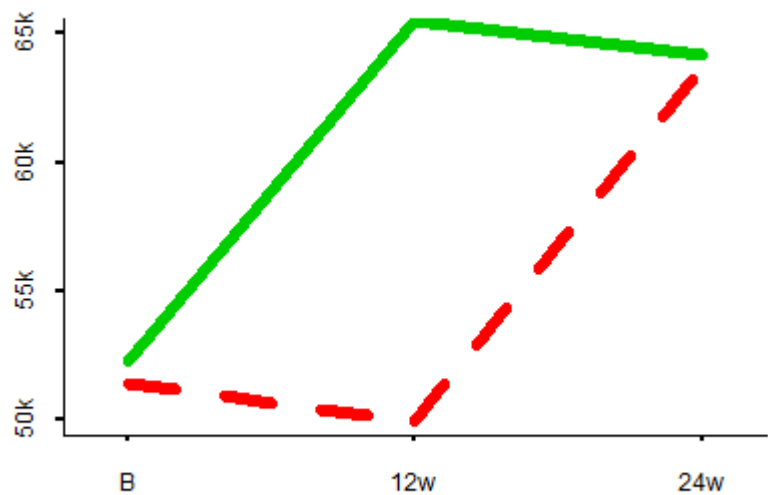


## West End Walkers 65+ (Walkers 65+)

- **Objective:** Pilot study, determine the effect of a pedometer-based walking intervention to increase walking through a primary care setting to Scottish adults aged  $\geq 65$ .
- **Design:** RCT of immediate intervention vs 12 week wait list control group
- **Outcome:** Step counts measured by pedometer and activPAL

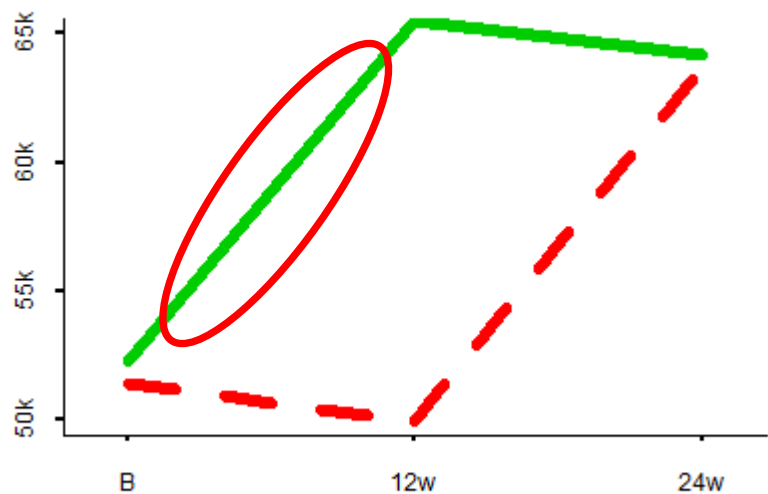


## Total weekly ActivPAL steps



--- Control  
— Intervention

## Total weekly ActivPAL steps

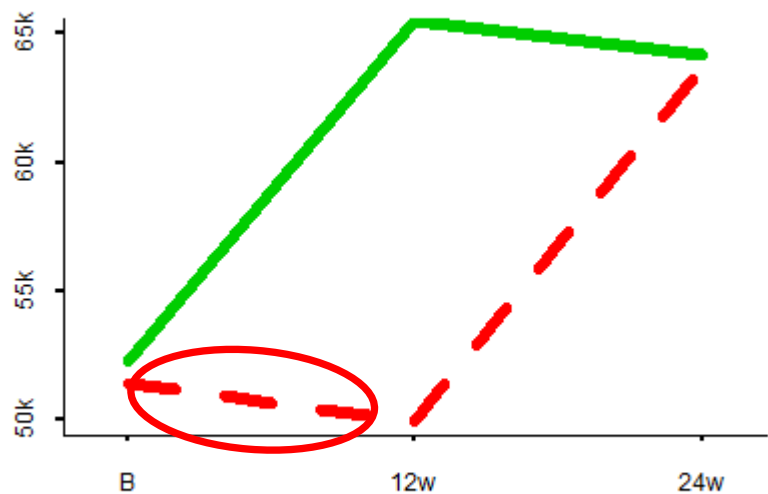


- - - Control  
 — Intervention

Effect	Estimate (95% CI)	p	Sample size
Change in step counts in immediate	15762 (7021 , 24504)	0.001	19



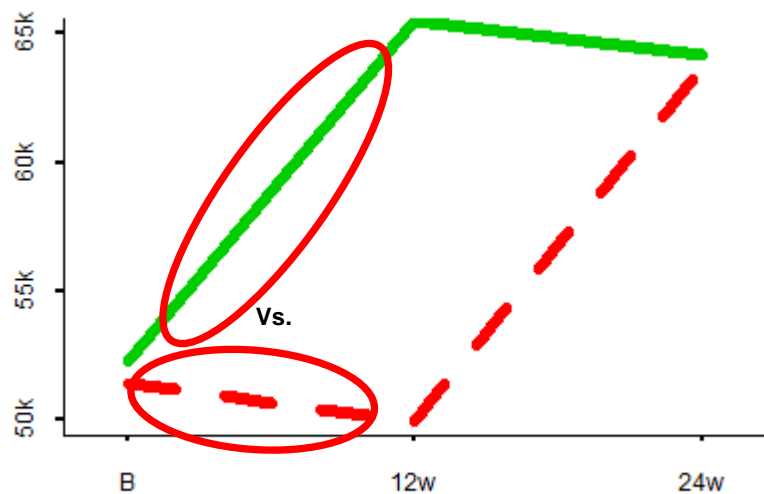
## Total weekly ActivPAL steps



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————— Intervention

Effect	Estimate (95% CI)	p	Sample size
Change in step counts in immediate	15762 (7021 , 24504)	0.001	19
Change in step counts in delayed	-2143 (-6349, 2063)	0.284	16

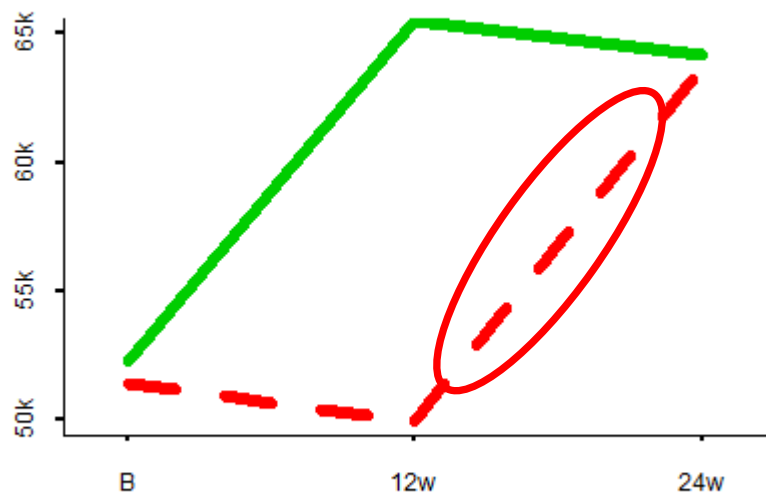
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Change in step counts in delayed	-2143 (-6349, 2063)	0.284	16
<b>Randomised treatment effect</b>	<b>17905 (7955, 27855)</b>	<b>&lt;0.001</b>	<b>19&amp;16</b>

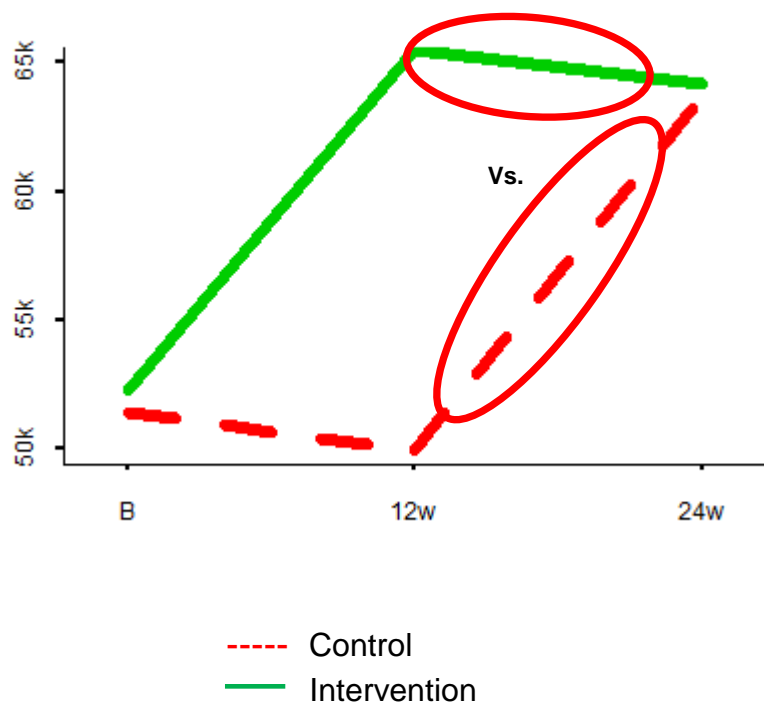
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- - - Control  
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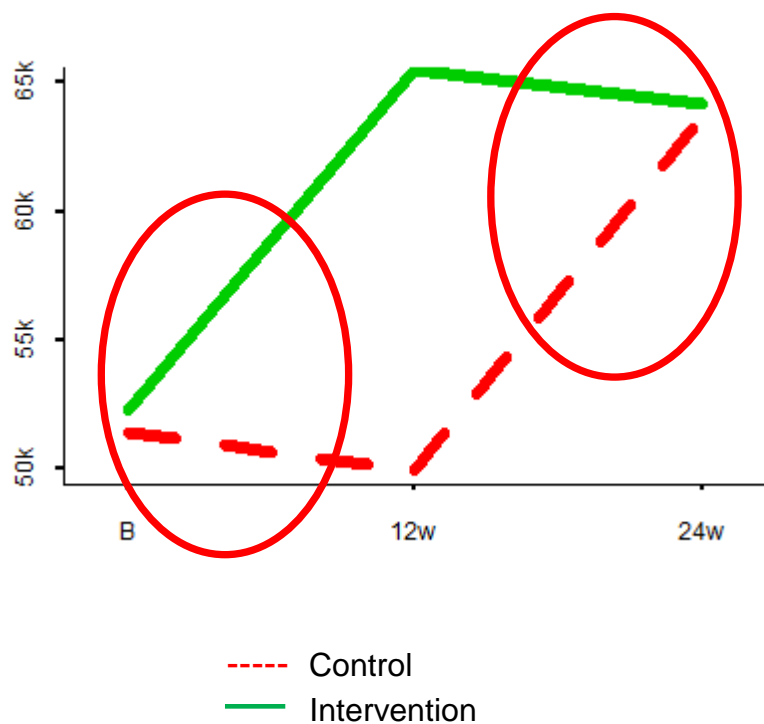
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Randomised treatment effect	17905 (7955, 27855)	<0.001	19&16
<b>Change in step counts in delayed</b>	<b>14749(7876 , 21622)</b>	<b>&lt;0.001</b>	<b>17</b>

## Total weekly ActivPAL steps



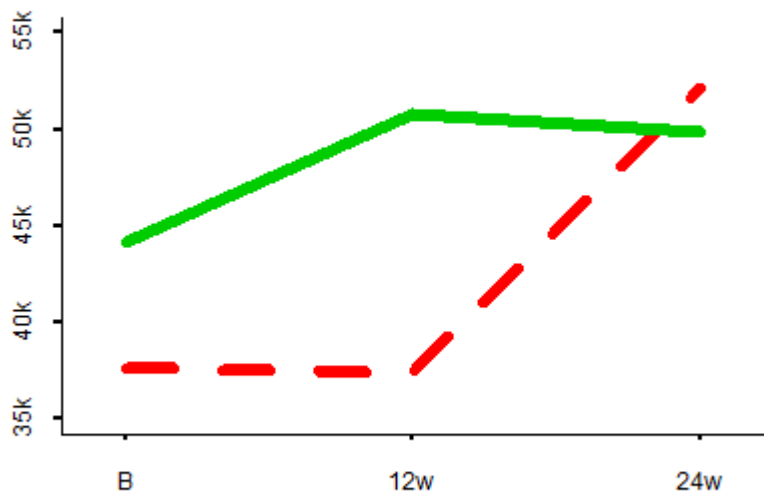
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Change in step counts in delayed	14749(7876 , 21622)	<0.001	17
<b>Treatment effect in delayed</b>	15507(4069 , 26944)	0.008	17&19

## Total weekly ActivPAL steps



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Change in step counts in delayed	14749(7876 , 21622)	<0.001	17
<b>Treatment effect in delayed</b>	<b>15507(4069 , 26944)</b>	<b>0.008</b>	<b>17&amp;19</b>
<b>Combined treatment effect</b>	<b>15252(5702 , 24802)</b>	<b>0.003</b>	<b>33</b>

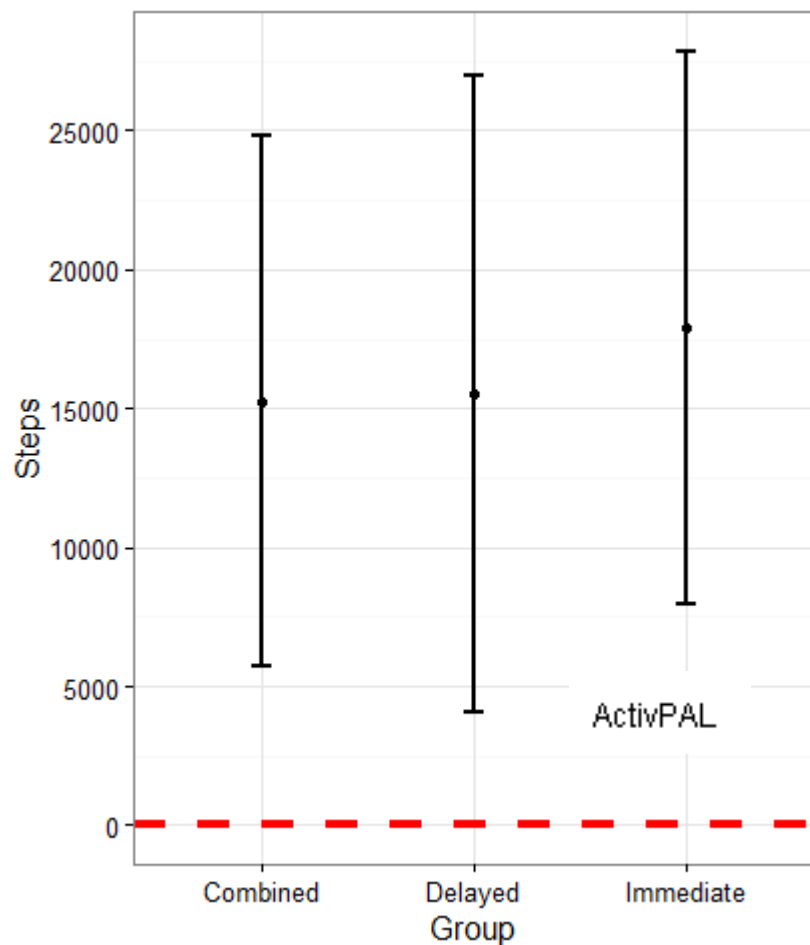
## Total weekly pedometer steps



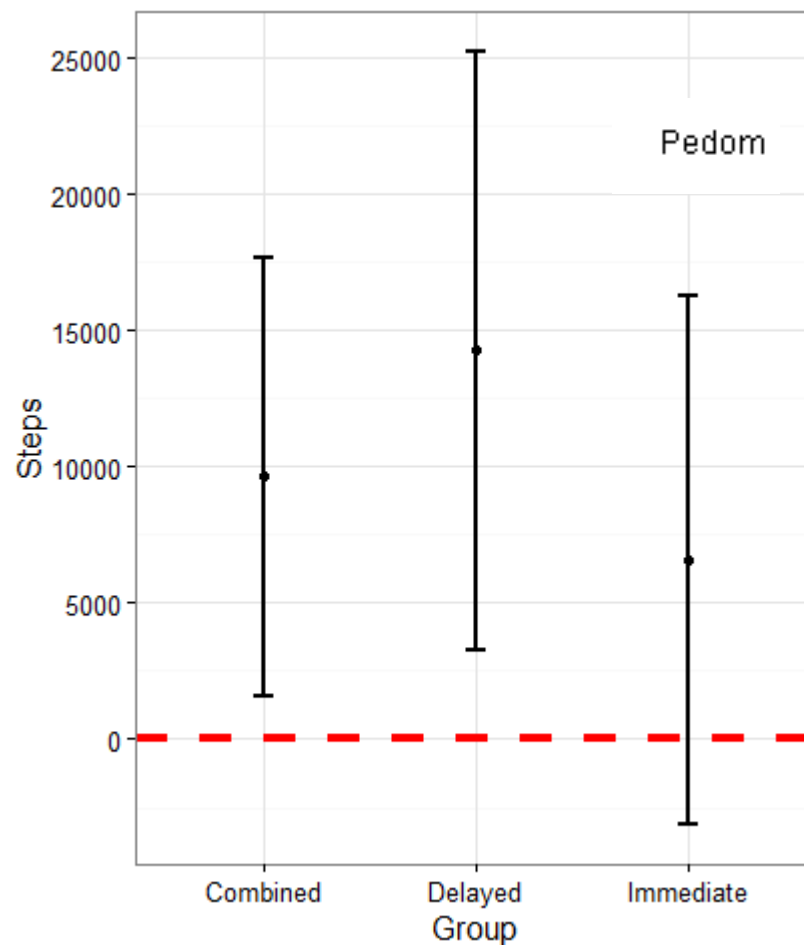
----- Control  
----- Intervention

Treatment Effect	Estimate (95% CI)	p
Randomised (Immediate)	6566 (-3157 , 16290)	0.177
Delayed	14256 (3271 , 25241)	0.010
Combined	9621 (1597 , 17645)	0.020

## Treatment effect



Published Results: Family Practice 2012; 29: 533-642

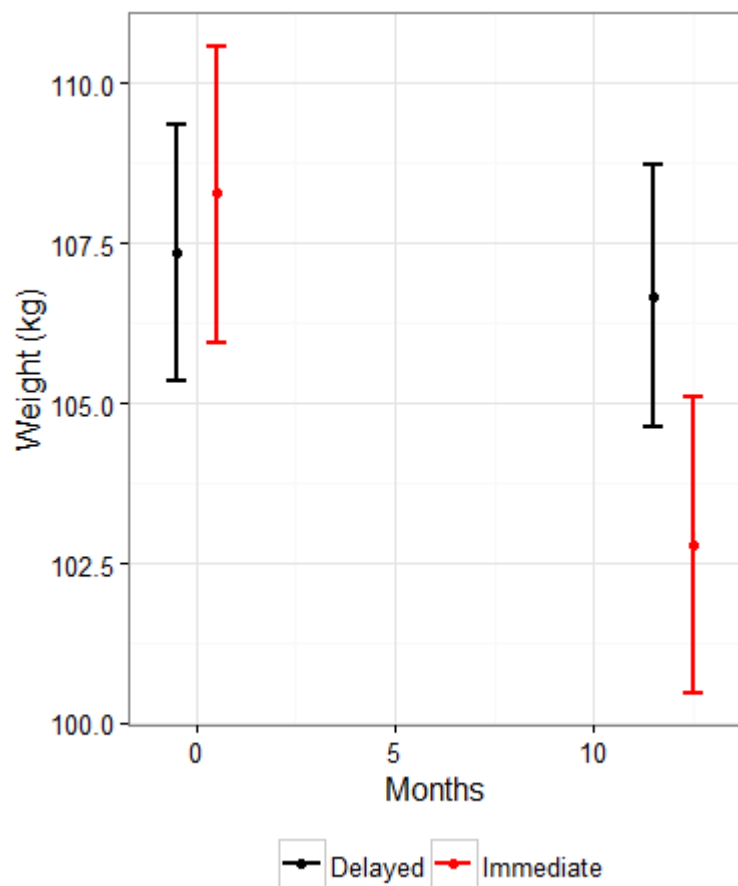


## Part 1: Football Fans in Training (FFIT)

- **Objective:** To assess the effectiveness of FFIT, a group-based, weight management programme in reducing weight for overweight males (35-65 years, BMI>28kg/m<sup>2</sup>)
- **Design:** RCT of immediate group vs 12 month wait list for comparison group
  - Comparison group received FFIT programme following 12 month final visit but no further data collected
- **Outcomes:** Mean difference in weight loss between groups at 12 months



## FFIT RCT results



Lancet 2014; 383: 1211-21

[www.ffit.org.uk](http://www.ffit.org.uk)

Weight Loss	Estimate (95% CI)	p
Immediate group	5.49 (4.45, 6.54)	<0.001
Delayed group	0.68 (-0.19, 1.54)	0.753
Between group difference	4.81 (3.61, 6.02)	<0.001*

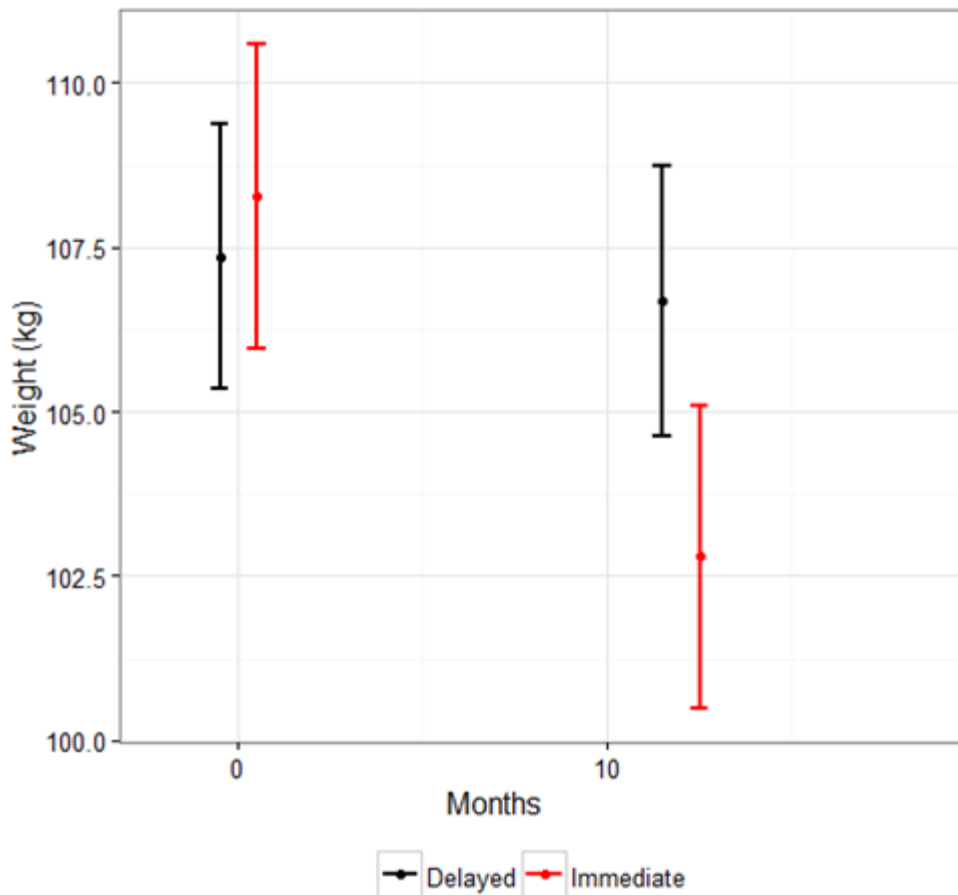


## Part 2: FFIT Follow-Up

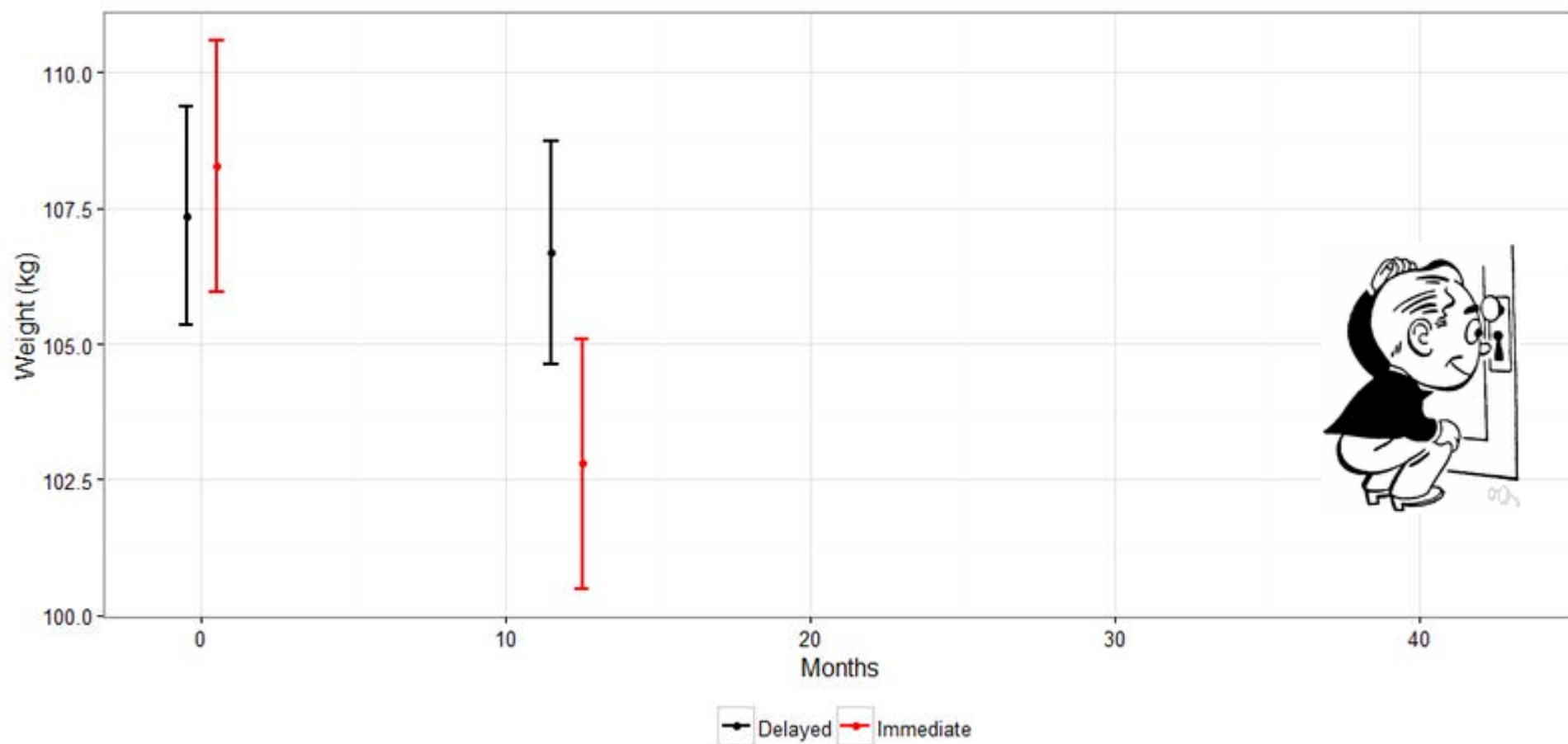
- **Objective:** Determine the extent to which both groups managed to sustain weight loss long term.
- **Design:** Longitudinal cohort follow-up of RCT participants 3.5 years after randomisation to FFIT.
- **Primary outcome:** Mean weight change from baseline to 3.5 years



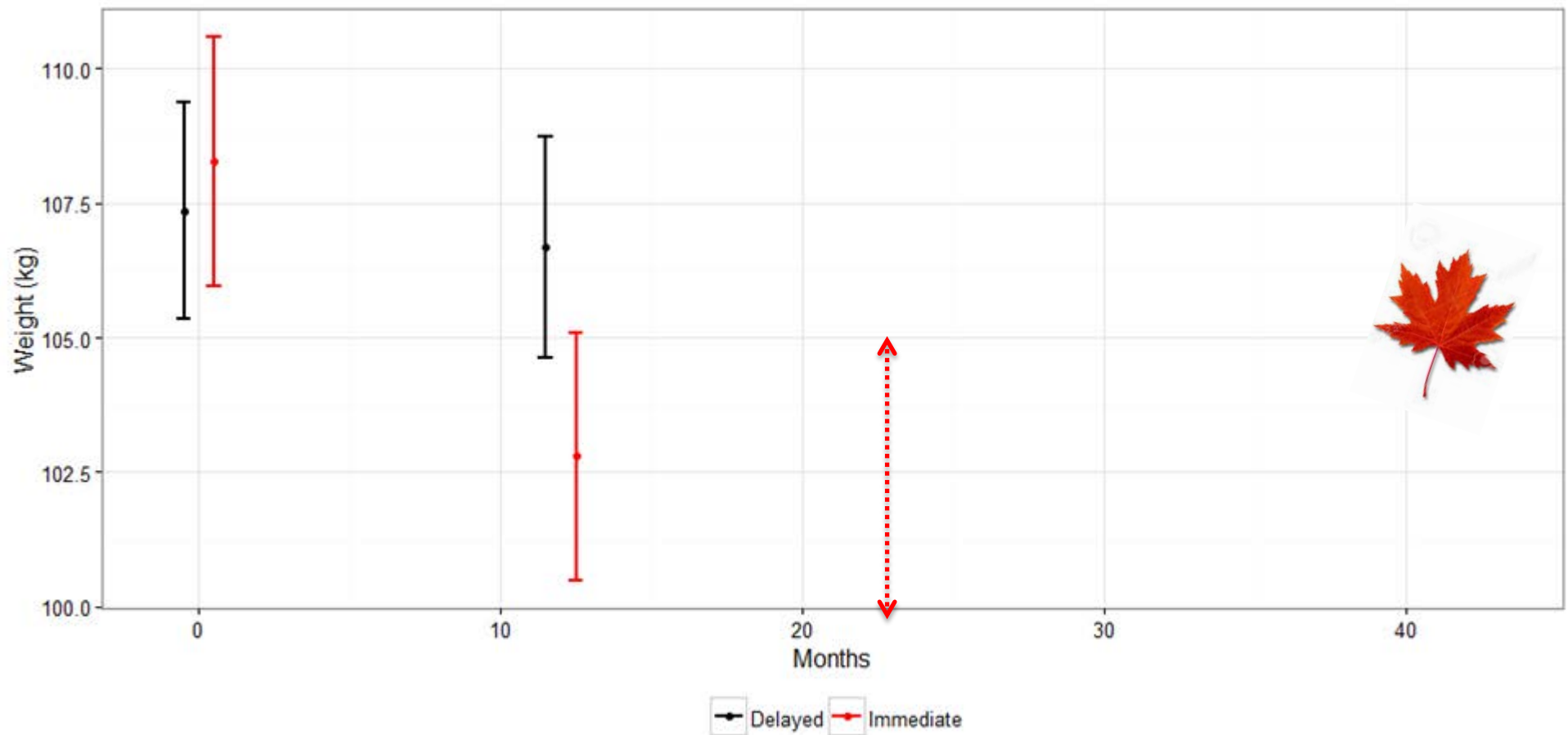
- **Results of the original FFIT RCT**



- Results of the original FFIT RCT + follow-up



- Results of the original FFIT RCT + follow-up



## Wait-listed control design

- Useful and acceptable to patients
- Primary analysis must be for randomised phase
- Additional follow-up data may add value
- Best built into original design, not as add on
- Potential biases must be considered

