Patients who get surgery, for example for orthopaedic reasons, are often advised by the doctors, subsequently to surgery, to get physiotherapy, that is, a series of exercises to help rehabilitation and more complete recovery. However, the costs of physiotherapy may often deter patients from following it. It is therefore important to try to show the potential benefits of physiotherapy, so that more patients can become convinced to follow it.

In the period of 4 years, three cooperating hospitals randomly assigned each of the 537 eligible patients, who had gone through an orthopeadic operation, in one of two groups: patients in the first group, $(Z_i = 1)$, were offered the opportunity to get physiotherapy at 50% reduced hospital fees; for patients assigned in the second group, physiotherapy was available at the standard cost.¹ For each patient, the recorded variables, in addition to assignment Z_i , are: whether or not the patient got physiotherapy, $W_i^{obs} = 1$ for yes, 0 for no; an assessment of the patient's recovery 3 months after surgery, $Y_i^{obs} = 1$ for satisfactory, 0 for unsatisfactory or poor. The assessment of this study's data was done by physicians blinded to both the assignment Z_i and the taking (or not) of physiotherapy by the patient. Table 1 gives the counts, n_{zwy} , of patients assigned $Z_i = z$ and with physiotherapy-taking status $W_i^{obs} = w$ and outcome $Y_i^{obs} = y$.

Z	W^{obs}	Y^{obs}	n
0	0	0	185
0	0	1	123
0	1	0	9
0	1	1	41
1	0	0	37
1	0	1	20
1	1	0	26
1	1	1	96

1. Estimate the intention-to-treat (ITT) effect of offering the discount on the improvement of recovery, Pr(Y(z=1)=1) - Pr(Y(z=0)=1), using an ITT analysis, that is, an analysis which does not use compliance data. Also give a standard error. Explain why, the ITT

¹The randomization probability, although equal for each patient, was not 50%. This, here, poses no problem in the subsequent discussion.

- effect can be different from the contrast that compares outcomes Y^{obs} of the patients who take vs. do not take physiotherapy.
- 2. In plain language of this setting, what are the four possible <u>pre-assignment</u> groups that the post-assignment taking of physiotherapy defines?
- 3. State in terms of potential outcomes the assumptions under which the randomizer Z_i is an "instrument", and, in plain language of this setting, discuss their plausibility.
- 4. Which of the assumptions in (3) is/are enough to estimate the proportion of "never-takers", i.e. patients who would not take physiotherapy whether or not they had been offered the discount in this study? Under this/these assumption(s), report estimates of the proportions of the groups defined in (2).
- 5. Define and, under the assumptions in (3), estimate the intention-to-treat effect (analogously to the estimand in (1)) for the "true-compliers" (i.e., those who would comply with both assignments). Also report a standard error for your estimate.
- 6. Discuss briefly (i) the clinical and (ii) the health policy implications of the difference between your estimates in (5) vs. (1).