Electronic Multidrug Punch Cards in Patients After Hospital Discharge - a Study Design

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Background

Various authors suggest that drug reminder packaging (e.g. pill boxes) may represent a simple method to help unintentionally non-adherent patients by facilitating drug management and by serving as a visual memory aid [1-3]. In Switzerland, multidrug punch cards (Figure 1) are frequently used for nursing home residents. We suppose that the potential of multidrug punch cards is larger and that any outpatient with a complex therapy plan benefits from such a system, independently of condition or age.

Hypothesis

Patients with multidrug punch card and feedback on their adherence behaviour will perform significantly better in clinical, adherence, and humanistic outcomes compared to patients with commercially available packaging and usual care.

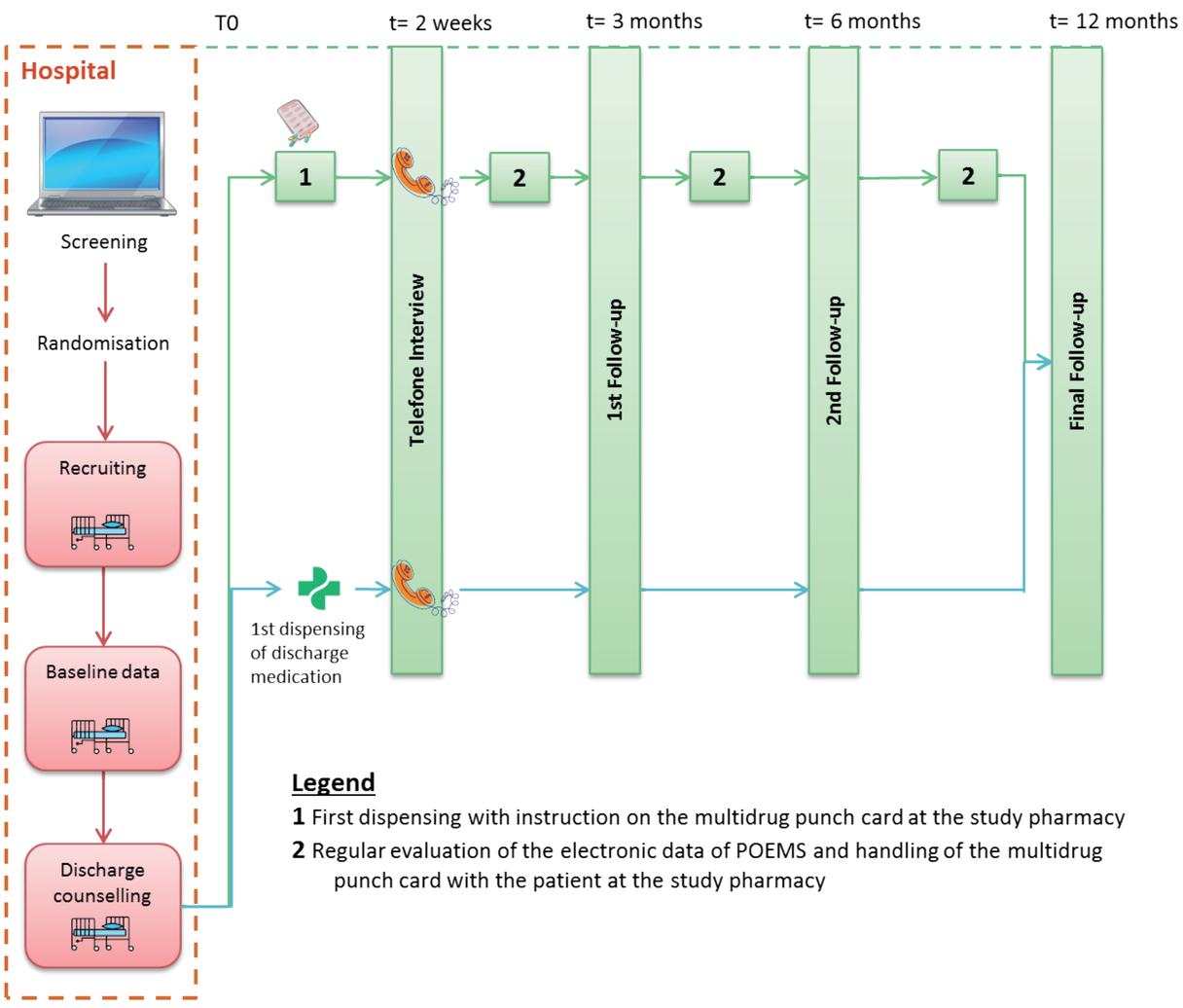
Methods

- Randomised controlled trial, two armed, open labelled
- Course of action:
  - Eligible patients are selected by screening (electronic) hospital records and randomised by a random sequence generator
  - Recruited patients are provided drug counselling by a pharmacist
  - After discharge, the intervention is implemented (T0)
  - Patients of the control group get usual care and their medication in commercially available packaging
  - Telefone interview after 2 weeks with all patients
  - Follow up visits at the study center at 3, 6, and 12 months with all patients

POEMS

We use **PO**lymedication **E**lectronic **M**easuring **S**ystem, an electronic film fixed on the back of the multidrug punch card, to measure timing and taking adherence of patients taking polymedication and to provide individual feedback on adherence behaviour (Figure 1-3) [4].

Study Design



Legend

1 First dispensing with instruction on the multidrug punch card at the study pharmacy

2 Regular evaluation of the electronic data of POEMS and handling of the multidrug punch card with the patient at the study pharmacy

Intervention

- Provision with all solid oral medication repackaged into electronic multidrug punch cards
- Individual feedback by a pharmacist on adherence behaviour based on the electronic profile of POEMS

Fig. 1: Multidrug punch card, front

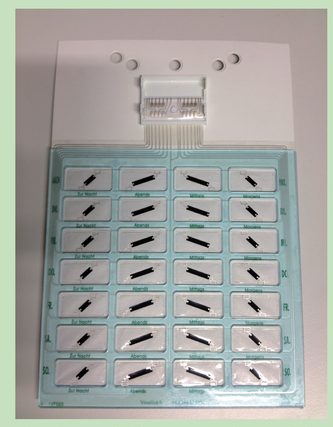


Fig. 2: Multidrug punch card, back

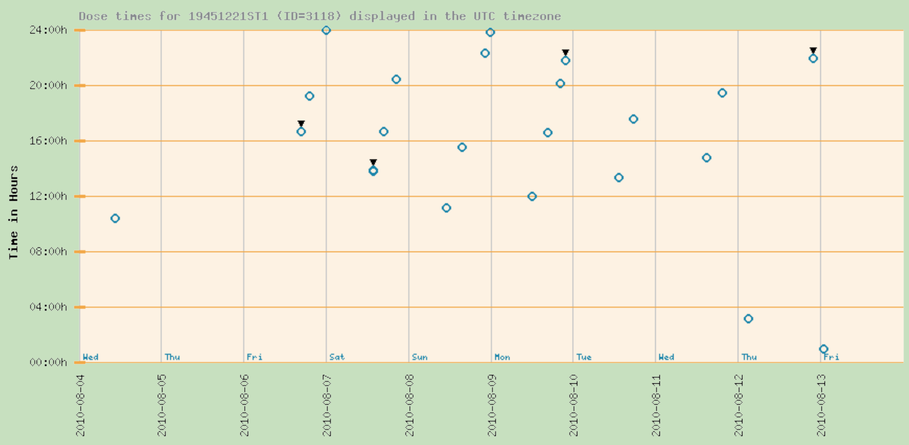


Fig. 3: 10-day patient profile from the electronic data of POEMS

Setting

Recruiting Place	University Hospital Basel, Switzerland
Population	All patients from the internal medicine‘s ward
Study sample	200 patients (pilot study: 20 patients)
Study duration	12 months
Study center	Notfall Apotheke Basel, Switzerland
Setting	Outpatients after hospital discharge, primary care by community pharmacies / study pharmacy

- **Inclusion criteria**: ≥ 18 years old, ≥ 4 different oral solid drugs prescribed at discharge, able to speak German, able to understand and sign the informed consent form, insured by a Swiss health insurance, management of medication alone or with the help of a relative, refill of medication at a community pharmacy, acceptance of a multidrug punch card, resident in the canton of Basel-Stadt or Basel-Landschaft
- **Exclusion criteria**: pregnancy, > 2 drugs not repackageable in a multidrug punch card, diagnosed dementia / evaluated as cognitively imparied by the nursing staff, transplanted, prescribed oral anticoagulation with vitamin K antagonists, has used a multidrug punch card or a singel dose system before, visually impaired, not able to push a tablet out of an commercially available medication blister, does not allow contact to GP / community pharmacy, is refered to a nursing home / another hosptial, is included in another clinical trial.

Outcomes

- Primary outcomes
  - Composite: time to rehospitalisation and time to major adjustment of therapy plan
  - Adherence: medication possession ratio (MPR)
- Secondary outcomes
  - Clinical: time to rehospitalisation, time to major adjustment of therapy
  - Adherence: timing adherence, taking adherence, time variability of drug intake according to POEMS, patient self report
  - Humanistic: Quality of Life (SF12), patient satisfaction

Outlook

Ethical approval was obtained by the Ethikkommission beider Basel, Switzerland (EKBB 54/12). The pilot study was startet on 21st of January 2013. After inclusion of 20 patients, procedures will be evaluated and adjusted. Study start of the main study is expected to be in June with 200 patients to be recruited in total.

Further details of the study are published on ClinicalTrials.gov under the identification number **NCT01759095**.

References

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