PLEASE NOTE: *This trial has been registered retrospectively.*

Trial Description

Title

Peer-supported Autonomy-Promoting Crisis Treatment

Trial Acronym

PACT

URL of the trial

[---]*

Brief Summary in Lay Language

Peer support for patients with severe mental illness is a recognized intervention and has been implemented in many stationary and outpatient mental health care facilities worldwide. Peers are people who had been in psychiatric care themselves and who want to support people in severe mental illness' on the basis of their own experience after they had been trained to do so. Aim of the study is to determine if and how the implementation of peer support in an acute psychiatric ward by trained peers affects patients and staff. Therefore, we questioned patients and staff in a psychiatric hospital before as well as 12 months after peer support had been implemented.

For each participating patient, the trial lasts six months. At baseline, the patient is asked regarding recovery, self-perception, his/her outlook on life, and self efficacy. Furthermore the patient is asked who he/she perceives staff, spaces, and atmosphere of the ward. The questioning lasts approximately and can be interrupted on demand. Six months after the patients was dismissed from Hospital, he/she will be questioned another time with regard to with mental health care Service receipt. This follow-up lasts about 15 min and can also be carried out via telephone.

Brief Summary in Scientific Language

Peer support for patients with severe mental illness is recognized as an innovative treatment intervention and has been implemented in many stationary and outpatient mental health care facilities worldwide. People who have experienced mental illness as well as its treatment (= peers) can bring a new quality of non-stigmatized, realistic, empowering support into psychosocial mental health care as proved by empirical data. Also, contemporary guidelines like the German S-3 Guideline for psychosocial therapies for People with severe mental illness`of the German Association for Psychiatry, Psychotherapy and Psychosomatics (Deutsche Gesellschaft für Psychiatrie und Psychotherapie, Psychosomatik und Nervenheilkunde - DGPPN) recommends peer support in routine care. Nevertheless, the implementation of peer support oftentimes is challenging and associated with several changes in different areas of care. So far, peer support is

hardly implemented in acute psychiatric care and seldomly integrated in existing treatment teams. Therefore, aim of the study is an evaluation of the efficacy of peer support in an acute psychiatric hospital. The study is going to analyze if peer support can enhance recovery, self efficacy, a more needs-based use and a better evaluation of care offers amongst patients. Furthermore, it will analyze if the implementation of peer support leads to higher recovery-orientation of the ward, to better ward climate, and to higher job satisfaction among staff. Additionally, it will be evaluated if the implementation of peer support leads to a decrease coercive measures. The study has a prospective, controlled clinical mixed-methods design with three follow-ups after baseline (pre t0, pre t1, post t0, post t1).

Do you plan to share individual participant data with other researchers?

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00015494**
- Date of Registration in DRKS: **2019/01/16**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **EA2/137/18 , Ethik-Kommission der Charité - Universitätsmedizin Berlin-**

Secondary IDs

Health condition or Problem studied

- ICD10: **F20 - Schizophrenia**
- ICD10: **F30 - Manic episode**
- ICD10: **F40 - Phobic anxiety disorders**
- ICD10: **F60 - Specific personality disorders**

Interventions/Observational Groups

- Arm 1: **Intervention group**
  Ahead of the implementation of peer support, 23 patients of a locked ward where peer support is going to be established will consecutively be included in the study from the 7th day of their stay at the ward (pre t0). From patient's point of view, individual recovery orientation (RSA-G), self-efficacy (SWE), and global functioning (GAF) will be assessed as well as socio-demographic, care-, and disease-related data and their perspective regarding recovery-orientation of the ward (RSA-D) at baseline. At the same time, all staff will be asked concerning their opinion regarding recovery-orientation of the ward (RSA-D), ward climate (EssenCES-D), and job satisfaction. Changes in kind, frequency, and duration of coercive measures (mechanical restraint, forced medication, limitation of freedom of movement) during the study period will be assessed through clinical routine data.
  Six months after having been dismissed from hospital (pre t1), all patients included in the trial will be contacted for assessing their use and evaluation of care offers (CSSRI).

  After baseline evaluation is finished, peer support will be implemented in the ward. Twelve months after baseline all variables assessed at baseline will be assessed again with staff and patients staying at the ward at that time.

  The same assessment will be carried out in an open ward where peer support is going to be implemented in the same way.

  Overall, 46 patients will be recruited for this study point in every intervention ward: 23 patients that did use one-to-one peer support during their stay at the acute ward and 23 did not do so.

  Within the scope of quality research, partly structured interviews will be conducted as well. On one hand, peers will be interviewed at baseline regarding their upcoming position and at post t0 regarding their actual experiences at the acute ward (n = 1 or 2 per ward). At the same study points, a random sample of staff (n = 11 per ward) will be questioned regarding the same topics in every intervention ward.
- Arm 2: **Control group: The study will be conducted as well in the other locked acute ward without peer support in the same hospital. This study arm only differs with regard to the amount of patients recruited (= 23 at pre t0 and n = 23 at post t0) and that no interviews will be conducted there.**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Non-randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Control group receives no treatment**
- Purpose: **Supportive care**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Recovery: It is assumed that patients who are treated in the acute ward twelve months after the implementation of peer support (intervention group post t0) show higher recovery than patients who were treated there prior to the implementation process (intervention group pre t0). Furthermore it is assumed that this parameter does not change in an acute ward without peer support (control group pre t0 – post t0).

Secondary Outcome

Self-efficacy: It is assumed that patients who are treated in the acute ward twelve months after the implementation of peer support (intervention groups post t0) show higher self-efficacy than patients who were treated there prior to the implementation process (intervention groups pre t0). Furthermore it is assumed that this parameter will not change in a an acute ward without peer support (control group pre t0 – post t0).

Recovery orientation of the ward: It is assumed that patients and staff evaluate the recovery orientation of the acute ward higher twelve months after the implementation of peer support (intervention groups post t0) than patients and staff did prior to the implementation process (intervention groups pre t0). Furthermore it is assumed that this parameter will not change in an acute ward without peer support (control groups pre t0 – post t0).

Use and evaluation of care offers: It is assumed that six months after their dismissal from hospital patients who were treated in the acute ward twelve months after the implementation of peer support (intervention groups post t1) show a more needs based use and better evaluation of outpatient, inpatient, and day-care offers than patients who were treated there prior to the implementation process (intervention groups pre t1). Furthermore it is assumed that this parameter will not change in an acute ward without peer support (control group pre t1 – post t1).

Coercive measures: It is assumed that twelve months after the implementation of peer support (intervention groups post t0) frequency and duration of coercive measures (mechanical restraint, forced medication, and limitation of freedom of movement) declined compared to the time prior to the implementation process (intervention groups pre t0). Furthermore it is assumed that this parameter will not change in an acute ward without peer support (control group pre t0 – post t0).

Ward climate and job satisfaction: It is assumed that staff evaluate their job satisfaction and the atmosphere of the ward higher twelve months after the implementation of peer support (intervention groups post t0) compared to their evaluation prior to the implementation process (intervention groups pre t0). Furthermore it is assumed that this parameter will not change in an acute ward without peer support (control group pre t0 – post t0).

Within the scope of an explorative study, semi-structured interviews with peer supporters and a random sample of staff are going to be conducted prior to the start of peer support in the acute ward (intervention groups pre t0) as well as twelve months after the implementation (intervention groups post t0) in order to assess their thoughts, fears, and expectations regarding their work or rather the implementation of peer support in the acute ward.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- Medical Center **Vivantes Klinikum Am Urban, Berlin**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2018/08/28**
- Target Sample Size: **197**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

Patients:
1. Patient has one of the following diagnosis´ as a main diagnosis: Schizophrenia, schizotypal and delusional disorders (F2X); Affective disorders (F3X); Neurotic, stress-related and somatoform disorders (F4X); Disorders of adult personality and behavior (F6X)
2. Patient has been at the ward for 7 days or longer
3. Patient is stable and has sufficient verbal and intellectual capacities (German language skills, no mental retardation, no dementia) in order to participate in the trial.
4. Patient is capable of giving consent.

Staff: All staff providing care in the relevant acute ward.

Exclusion criteria

Patient refuses to participate in the trial.

Addresses

- **Primary Sponsor**

  Vivantes Klinikum Am Urban, Klinik für Psychiatrie und Psychotherapie

Primary Sponsor

Vivantes Klinikum Am Urban, Klinik für Psychiatrie und Psychotherapie
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10967 Berlin
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URL: **https://www.vivantes.de/fuer-sie-vor-ort/klinikum-am-urban/fachbereiche/kliniken/psychiatrie-psychotherapie-und-psychosomatik/**

■ **Contact for Scientific Queries**

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Sources of Monetary or Material Support

■ **Institutional budget, no external funding (budget of sponsor/PI)**

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Institutional budget, no external funding (budget of sponsor/PI)

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URL: **https://www.vivantes.de/fuer-sie-vor-ort/klinikum-am-urban/fachbereiche/kliniken/psychiatrie-psychotherapie-und-psychosomatik/**

Status

- Recruitment Status: **Recruiting ongoing**
- Study Closing (LPLV): **[---]***

Trial Publications, Results and other documents

- Approval of ethics comm. (mandatory for transfer to Studybox) **Ethikvotum Amendment April 2019**
- trial protocol (mandatory for transfer to Studybox) **Studienprotokoll_PACT_erweitert**

** This entry means the parameter is not applicable or has not been set.*

**** This entry means that data is not displayed due to insufficient data privacy clearing.*