

- (ii) if there were no SAEs, this should be clearly stated
- (iii) if SAEs were not monitored, this should be listed as a study limitation.
- (c) Hospital admissions:
 - (i) hospital admissions should always be reported as adverse events, even when admission is a study outcome
 - (ii) if there were none, this should be clearly stated
 - (iii) should be supplemented with data on usage of crisis services if possible
 - (iv) if admissions were not monitored, this should be listed as a study limitation.
- (d) Adverse events:
 - (i) list which instances of less serious adverse events were monitored
 - (ii) list how they were monitored (e.g. case note review).
 - (iii) provide detailed descriptions of any adverse events that occur.
- (e) Side-effects:
 - (i) include standardised patient-reported measure of side-effects.
- (f) Symptom deterioration:
 - (i) all instances of clinically meaningful deterioration in symptoms or psychological functioning should be reported.
- (g) Drop out:
 - (i) report study drop out, and reason for drop out (including direct or indirect link to harm), by treatment arm
 - (ii) report separately drop out and non-completion of therapy.
- (h) Public and patient involvement (PPI):
 - (i) ensure meaningful PPI in decision-making about how harm is operationalised and monitored.

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Psychiatry in history

The Külliye of Sultan Bayezid II

Aykan Pulular  and Raymond Levy

In medieval times under the Ottoman Empire the mentally ill were treated with dignity and humanity. Restraints were minimal and might consist of a thin silver cord. One of the examples left today is in the Turkish city of Edirne, second capital of the Ottoman Empire and principal centre of Thrace, where there stands the Külliye ('Complex') of Sultan Bayezid II. Built in 1488, during a period when the mentally ill were generally treated badly, the hospital within the Külliye used an approach that was ahead of its time. There were three parts to treatment: music, the sound of running water and a variety of different scents. This approach was widespread throughout the empire in what were known as *bimaristan* or *darussyifa*. Examples can still be seen in Damascus, Aleppo and Cairo as well as in Bursa and Istanbul. The complex comprised a medical school (*madrasah*), a hospital (*darussyifa*) for both physical disorders and the insane, an *imaret* (the social aid unit that served free food to the poor and the staff in the Külliye), a mosque, guesthouses, a *muvaqqithane* (a unit that was concerned with the calendar and the time of the day), Turkish baths, a watermill and a bridge. Today only some parts of the complex survive: the small mosque, the madrasah and the *darussyifa*.

There were three sections in the *darussyifa*. The first was for out-patient services, the second was for the staff and the third served as an in-patient ward. Its architectural design was based on a central system positioned so as to use relatively few staff. This section consisted of a big hall covered by a high dome, with six winter rooms and four summer rooms around it and a stage for the musicians. In the middle of the hall a fountain ran water over the sloping floor to a gutter designed to collect the overflow. It also provided a source for washing the patients. The tranquillising sound of the running water from the fountain, combined with the scents of various herbs and flowers such as jasmine, carnation, tulip and hyacinth, was used to alleviate patients' anxiety. The musicians played three times a week, and different modes of Turkish classical music were used for each illness. The dome of the hall provided a particularly good acoustic.

Although we do not know how successful these methods were, we can assume that they were at least relatively humane and ahead of their time. The Külliye in Edirne was fully restored and reopened its doors to visitors as a museum in 1997. It was awarded the Council of Europe Museum Prize for the year 2004.

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