Placebo

Placebo is an abused word in trials. The most egregious misuses stem from use as an adjective, eg, as in placebo patient or placebo group – meaning, strictly speaking, a sugar-coated person or group.

There is treatment involving use of a placebo but there is no placebo treatment. It is common to use placebos in trials as a masking device to keep patient and clinic staff from knowing whether the substance being tested is an active drug or matching placebo, but the "treatment" a person receives, is "best medical care" plus the assigned treatment. For example, all persons enrolled in the UGDP received counseling regarding an antidiabetic diet plus the assigned treatment.

placebo adj - 1. Of or relating to the use or administration of a placebo. 2. Of or relating to something considered to be useless or ineffective. Usage note: Limit use to the sense of defn 1. Avoid nonsensical uses such as when the term serves as an adjective for patient or group, as in placebo patient or placebo group; use placebo-assigned or placebo-treated instead. See also notes for placebo and placebo patient.

placebo n - [ME, fr L, I shall please, fr placère to please; the first word of the first antiphon of the service for the dead, I shall please the Lord in the land of the living, fr Roman Catholic vespers] 1. A pharmacologically inactive substance given as a substitute for an active substance, especially when the person taking or receiving it is not informed whether it is an active or inactive substance. 2. placebo treatment (defn 1) 3. A sugar-coated pill made of lactose or some other pharmacologically inert substance. 4. Any medication considered to be useless, especially one administered in pill form. 5. nil treatment 6. An ineffective treatment. rt: double placebo, experimental placebo, homeopathic dose, multiple placebo, nocebo, placebo treatment, sham, sham procedure, therapeutic placebo Usage note: Subject to varying use. Avoid in the sense of defns 4, 5, and 6; best not used interchangeably with sham (see usage note for sham). The use of a placebo should not be construed to imply the absence of treatment. Virtually all clinical trials involve care and investigators conducting them are obligated to meet standards of care, regardless of treatment assignment and whether masked or not. As a result, a control treatment involving use of a placebo is best thought of as a care regimen with placebo substituting for one element of the care regimen. Labels such as placebo patient or placebo group create the impression that patients assigned to receive placebos are left untreated. The labels (in addition to being wrong in the literal sense of usage; see placebo patient for comment) are misleading when placebo treatment is in addition to other treatments (eg, as in the University Group Diabetes Program where all patients received dietary counseling or in a vaccine trial where infants receive vaccines for diphtheria and tetanus in addition to a pertussis vaccine or matching placebo). See also placebo treatment.

placebo group n - 1. placebo-assigned group 2. placebo-treated group 3. A group not receiving or not having received any treatment. Usage note: Avoid for the reasons stated in the usage note for placebo patient.

placebo patient n - 1. placebo-assigned patient 2. placebo-treated patient 3. A study patient who does not receive any treatment. Usage note: Literally, a sugar-coated patient, ala defn 3 for placebo. Use placebo-assigned patient or placebo-treated patient for uses in the sense of defns 1 and 2, respectively; avoid in the sense of defn 3.

placebo treatment n - 1. A treatment involving the use of a placebo. 2. placebo-control treatment (defn 1) 3. An ineffective or useless treatment used as a control treatment (not recommended usage). syn: mock treatment rt: adjunctive treatment, control treatment, experimental placebo, sham treatment, therapeutic placebo Usage note: Subject to misuse when used in the
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sense of defn 3. Not to be confused with nontreatment as represented in trials with a nil treatment control. Also not to be confused with sham treatment. Use of the adjective modifier placebo should be reserved for settings in which a placebo is actually used, as in the sense of defns 1 or 2 for placebo.

Other related words or terms

placebo control n - 1. placebo-control treatment 2. A treatment involving the use of a placebo.

Usage note: See placebo treatment.

placebo effect n - 1. The effect produced by a placebo; assessed or measured against the effect expected or observed in the absence of any treatment. 2. The effect produced by an inactive control treatment, especially one involving use of a placebo. 3. The effect produced by a control treatment considered to be nil or ineffective. 4. An effect attributable to a placebo; an effect attributable to a placebo. rt: sham effect Usage note: Limit usage to settings involving the actual use of a placebo. Avoid in the sense of defns 2 and 3 when the control treatment does not involve use of a placebo.

placebo lead-in period n - [trials] A lead-in period in which persons receive a placebo treatment (as in the Coronary Drug Project [Coronary Drug Project Research Group, 1973]2) for a time prior to enrollment and treatment assignment; typically done to help identify compliant individuals. See Brittain and Wittes [1990]3 for discussion of the usefulness of such strategies. syn: placebo run-in period rt: lead-in period, shakedown period.

placebo period n - [trials] A period of time in which a person (treatment unit), to be enrolled or already enrolled, receives a placebo (usually administered either in single- or double-masked fashion); when such a period precedes treatment assignment, usually referred to as placebo lead-in period or as placebo run-in period and used to aid in the selection of compliant persons or to facilitate the assessment of eligibility. Periods occurring after enrollment may arise in relation to washouts or cessations of assigned treatment in relation to episodes of intercurrent illnesses. rt: lead-in period, shakedown period

placebo reactor n - 1. A person who reports side effects normally associated with the test treatment while receiving a placebo. 2. A person who reacts to a placebo as indicated by symptoms or complaints similar to those experienced with the test treatment(s).

placebo run-in period n - placebo lead-in period

placebo treatment effect n - 1. The effect produced, or capable of being produced, by a placebo treatment (defn 1). 2. The effect produced, or capable of being produced, by an inactive control treatment; placebo treatment (defn 3). Usage note: Subject to misuse when used in the sense of defn 2. Use of the adjective modifier placebo should be reserved for settings in which a placebo is actually used, as in the sense of defns 1 or 2 for placebo.

placebo washout n - Administration of a placebo for a defined period of time following administration of a test treatment to allow time for re-establishment of a baseline. Common in crossover trials following each treatment and prior to administration of the next one; usually administered in single-masked or double-masked fashion. rt: washout period

placebo-assigned adj - 1. Of, related to, or being assigned to receive a placebo treatment. 2. Of,
related to, or being assigned to receive an **inactive treatment**. rt: **placebo-treated**

*Usage note:* Use only in the sense of defn 1; avoid as an adjective modifier in the sense of defn 2 except when a **placebo** (defns 1 or 2) is used. See **placebo treatment** for added comments.

**placebo-assigned group** n - [trials] 1. The **group** of persons or **treatment units** assigned to a **placebo-control treatment** (defn 1). 2. The group of persons or treatment units assigned to an **inactive control treatment**. rt: **placebo-assigned patient, placebo-treated group**

*Usage note:* Use only in the sense of defn 1; avoid in the sense of defn 2 when a **placebo** (defns 1 or 2) is not used. See **placebo treatment** for added comments.

**placebo-assigned patient** n - [trial] 1. A **patient assigned** to receive a **placebo treatment**. 2. A patient assigned to receive an **inactive control treatment**. rt: **placebo-assigned group, placebo-treated patient**

*Usage note:* Use only in the sense of defn 1; avoid in the sense of defn 2 when a **placebo** (defns 1 or 2) is not used. See **placebo treatment** for added comments.

**placebo-control** adj - Of, related to, or concerned with a **placebo control**.

**placebo-control treatment** n - 1. An **inactive control treatment** involving administration of a **placebo** in single-masked or double-masked fashion. 2. Any **inactive control treatment**, including those not involving administration of a placebo. rt: **study treatment**

*Usage note:* Use in the sense of defn 1. Avoid in the sense of defn 2 except when a **placebo** is not used. See **placebo treatment** for added comments.

**placebo-controlled** adj - Of, relating to, or being **controlled** by use of a **placebo**.

**placebo-controlled clinical trial** n - 1. A **clinical trial** in which the **control treatment** involves the administration of a **placebo**. 2. A clinical trial involving an **inactive control treatment**. Usage note: Avoid in the sense of defn 2 except when a **placebo** is used. See **placebo treatment** for added comments.

**placebo-controlled trial** n - 1. A **trial** in which the **control treatment** involves the administration of a **placebo**. 2. A trial involving an **inactive control treatment**. Usage note: Avoid in the sense of defn 2 except where a **placebo** is used. See **placebo treatment** for added comments.

**placebo-treated** adj - 1. **placebo-assigned** (defn 1) 2. Of, related to, or being **treated** with a **placebo**. 3. Of, related to, or being treated with an **inactive treatment**. rt: **placebo-assigned**

*Usage note:* Use only in the sense of defn 2; avoid as an adjective modifier in the sense of defn 3 except where a **placebo** (defns 1 or 2) is used. Use **placebo-assigned** instead of **placebo-treated** when used in the sense of defn 1. See **placebo treatment** for added comments.

**placebo-treated group** n - [trials] 1. The group of persons or treatment assignment units receiving or that have received a **placebo** (defns 1 or 2). 2. The group of persons or treatment units that receive an **inactive control treatment**. 3. The **group** of persons or **treatment assignment units** assigned to a **placebo-control treatment, placebo-assigned group**. 4. The group of persons or treatment units assigned to receive an inactive control treatment. rt: **placebo-treated patient, placebo-assigned group**

*Usage note:* Subject to misuse. Use only in the sense of defn 1. Often used in the sense of defn 3 as a synonym for **placebo-assigned group** (defn 1); avoid by using **placebo-assigned group** (since there may not be a one-to-one correspondence between being
placebo-assigned and being placebo-treated). Avoid in the sense of defn 4; use placebo-assigned group if the inactive treatment involves use of a placebo (defns 1 or 2). Avoid in the sense of defn 2 when a placebo (defns 1 or 2) is not used. See placebo treatment for added comments.

placebo-treated patient n - 1. A patient receiving a placebo (defns 1 or 2). 2. A patient receiving an inactive control treatment. 3. A patient assigned to a placebo-control treatment; placebo-assigned patient. 4. A patient assigned to an inactive control treatment. rt: placebo-treated group, placebo-assigned patient Usage note: Subject to misuse. Use only in the sense of defn 1. Often used in the sense of defn 3 as a synonym for placebo-assigned patient (defn 1); avoid by using placebo-assigned patient (since usually there is not a one-to-one correspondence between being placebo-assigned and being placebo-treated). Avoid in the sense of defn 2 when a placebo (defns 1 or 2) is not used. Avoid in the sense of defn 4; use placebo-assigned patient when a placebo (defns 1 or 2) is used. See placebo treatment for added comments.

References
