

Disclosure of Information to Potential Subjects on Research Recruitment Web Sites

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Table 1: Recruitment Web Sites for Diabetes and Depression Studies: Characteristics and Differences Associated with Listing of Financial Incentives

| Study characteristics mentioned on Web site | DIABETES | | | DEPRESSION | | | DIABETES vs. DEPRESSION |
|--|-----------------------------|---|----------------------|-----------------------------|---|----------------------|-------------------------|
| | All studies (total N = 171) | Studies that list financial incentives (total N = 93) | p-value ^a | All studies (total N = 184) | Studies that list financial incentives (total N = 84) | p-value ^a | p-value ^b |
| Any incentive ^c | 125 (73.1%) | N/A | N/A | 138 (75.0%) | N/A | N/A | NS |
| Any financial incentive | 93 (54.4%) | N/A | N/A | 84 (45.7%) | N/A | N/A | 0.062 |
| Specific amount of incentive | 21 (12.3%) | 21 (22.6%) | N/A | 36 (19.6%) | 36 (42.9%) | N/A | 0.042 |
| Nonmonetary incentive (e.g., free medication, treatment, evaluation) | 81 (47.4%) | 49 (52.7%) | 0.086 | 114 (62.0%) | 55 (65.5%) | NS | 0.004 |
| Number of visits | 58 (33.9%) | 35 (37.6%) | NS | 33 (17.9%) | 22 (26.2%) | 0.006 | 0.000 |
| Study length | 74 (43.3%) | 46 (49.5%) | 0.051 | 69 (37.5%) | 30 (35.7%) | NS | NS |
| Any procedure that appears more than minimal risk (includes administration of drug or device and/or assessment—e.g., LP) | 115 (67.3%) | 58 (62.4%) | 0.093 | 142 (77.2%) | 57 (67.9%) | 0.005 | 0.024 |
| Intervention that appears more than minimal risk (e.g., administration of active drug or device) | 115 (67.3%) | 58 (62.4%) | 0.093 | 140 (76.1%) | 55 (65.6%) | 0.002 | 0.042 |
| Additional procedures that appear more than minimal risk ^{d, e} | 4 (2.3%) | 1 (1.1%) | | 2 (1.1%) | 2 (2.4%) | | |
| Clinical trial | 107 (62.6%) | 55 (59.1%) | NS | 124 (67.4%) | 54 (64.3%) | NS | NS |
| Source of funding listed ^f | 4 (2.3%) | 2 (2.2%) | N/A | 25 (13.6%) | 12 (14.3%) | N/A | N/A |
| Type of funding, if listed | | | | | | | |
| For-profit | 1 (0.6%) | 0 (0.0%) | N/A | 0 (0.0%) | 0 (0.0%) | N/A | N/A |
| Not-for-profit | 3 (1.8%) | 2 (2.2%) | N/A | 25 (13.6%) | 12 (14.3%) | N/A | N/A |
| Unlisted | 167 (97.7%) | 91 (97.8%) | N/A | 159 (86.4%) | 72 (85.7%) | N/A | N/A |
| Type of institutional affiliation of contact ^f | | | NS | | | NS | 0.008 |
| For-profit | 82 (48.0%) | 45 (48.4%) | N/A | 70 (38.0%) | 34 (40.5%) | N/A | N/A |
| Not-for-profit | 75 (43.9%) | 44 (47.3%) | N/A | 111 (60.3%) | 49 (58.3%) | N/A | N/A |
| Unlisted | 14 (8.2%) | 4 (4.3%) | N/A | 3 (1.6%) | 1 (1.2%) | N/A | N/A |

a. P-values represent results of a Fisher's Exact Test comparing rates of mention of incentive with rates of mention of other study characteristics.

b. P-values represent results of a Fisher's Exact Test comparing rates of mention of various study characteristics between disease categories.

c. Incentives include financial compensation, free medical treatment, free medicine, and other nonmonetary incentives.

d. For example, lumbar puncture, but not administration of a medication or device.

e. Chi square statistics were not computed, since sample sizes were too small.

f. In statistical analyses, we excluded those sites whose type of institutional affiliation of contact was unlisted.

Table 2: Diabetes and Depression Studies Listed on Web Sites: Differences between Studies That Appear More Than Minimal Risk^a vs. Not More Than Minimal Risk

| Information listed | DIABETES | | | DEPRESSION | | | DIABETES VS. DEPRESSION |
|--|--|---|----------------------|--|---|----------------------|-------------------------|
| | Study appears more than minimal risk (total N = 115) | Study does not appear more than minimal risk (total N = 56) | p-value ^b | Study appears more than minimal risk (total N = 142) | Study does not appear more than minimal risk (total N = 42) | p-value ^b | p-value ^c |
| Any incentive ^d | 86 (74.8%) | 41 (73.2%) | NS | 104 (73.2%) | 34 (81.0%) | NS | NS |
| Any financial incentive | 58 (50.4%) | 35 (62.5%) | 0.093 | 57 (40.1%) | 27 (64.3%) | 0.005 | 0.064 |
| Specific amount of incentive | 18 (15.7%) | 3 (5.4%) | 0.041 | 19 (13.4%) | 17 (40.5%) | 0.000 | NS |
| Nonmonetary incentive (e.g., free medication, treatment, evaluation) | 69 (60.0%) | 10 (17.9%) | 0.000 | 99 (69.7%) | 15 (35.7) | 0.000 | 0.067 |
| Number of visits | 35 (30.4%) | 23 (41.1%) | NS | 21 (14.8%) | 12 (28.6) | 0.038 | 0.002 |
| Study length | 49 (42.6%) | 25 (44.6%) | NS | 53 (37.3%) | 16 (38.1) | NS | NS |
| Assessment involving more than minimal risk ^{e, f} | 4 (3.5%) | 0 (0.0%) | N/A | 0 (0.0%) | 2 (4.8%) | N/A | N/A |
| Clinical trial | 105 (91.3%) | 2 (3.6%) | 0.000 | 117 (82.4%) | 7 (16.7%) | 0.000 | 0.028 |
| Source of funding listed | 1 (0.9%) | 3 (5.4%) | N/A | 16 (11.3%) | 9 (21.4%) | N/A | N/A |
| Type of funding, if listed ^f | | | | | | | |
| For-profit | 0 (0.0%) | 0 (0.0%) | N/A | 0 (0.0%) | 0 (0.0%) | N/A | N/A |
| Not-for-profit | 1 (0.9%) | 3 (5.4%) | N/A | 16 (11.3%) | 9 (21.4%) | N/A | N/A |
| Unlisted | 114 (99.1%) | 53 (94.6%) | N/A | 126 (88.7%) | 33 (78.6%) | N/A | N/A |
| Type of institutional affiliation of contact ^g | | | 0.000 | | | 0.001 | 0.008 |
| For-profit | 78 (67.8%) | 4 (7.1%) | N/A | 76 (53.5%) | 35 (83.3%) | N/A | N/A |
| Not-for-profit | 33 (28.7%) | 42 (75.0%) | N/A | 63 (44.4%) | 7 (16.7%) | N/A | N/A |
| Unlisted | 4 (3.5%) | 10 (17.9%) | N/A | 3 (2.1%) | 0 (0.0%) | N/A | N/A |

a. P-values represent results of Fisher's Exact Tests comparing mention of more than minimal risk assessment or procedure and other study characteristics.

b. P-values represent results of Fisher's Exact Tests comparing mention of study characteristics in more than minimal risk studies between disease categories.

c. Incentive includes financial compensation, free medical treatment, free medicine, and other nonmonetary incentives.

d. For example, administration of drug or device and/or assessment (e.g., LP).

e. For example, lumbar puncture, but not administration of a medication or device.

f. Chi square statistics were not computed, since cell sizes were too small.

g. In statistical analyses, we excluded those sites whose type of institutional affiliation of contact was unknown.

Table 3: Associations between Apparent Imbalance of Information^a and Type of Institutional Affiliation of Contact

| | <i>DIABETES</i> | | <i>DEPRESSION</i> | | <i>DIABETES & DEPRESSION</i> | |
|--|--------------------------|----------------|--------------------------|----------------|----------------------------------|----------------|
| | <i>N (%)^b</i> | <i>p-value</i> | <i>N (%)^b</i> | <i>p-value</i> | <i>N (%)^b</i> | <i>p-value</i> |
| Apparently imbalanced presentation of information ^a | 58 (33.9%) | 0.000 | 78 (42.4%) | 0.000 | 136 (38.3%) | 0.00 |
| Not-for-profit affiliation of contact | 14 (8.2%) | | 32 (17.4%) | | 46 (13.0%) | |
| For-profit affiliation of contact | 44 (25.7%) | | 46 (25.0%) | | 90 (25.4%) | |

a. Assessed as mentioning incentives but not requirements for study (i.e., number of visits and/or length of study).

b. Percentages are shown as proportion of total number of studies sampled for each disease (i.e., 171 and 184, respectively).