Perceptions Of Research Procedures, Informed Consent, And Therapeutic Misconception Among Egyptian Research Participants

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Background

- Informed consent is essential to ensure
  - Protection of the rights and interests of participants
  - Respect of participants’ autonomy
- Participation in clinical research should always be on a voluntary basis
Background

- Participants need to
  - Differentiate between research and clinical care (therapeutic misconception),
  - To avoid underestimation of risk or overestimation of benefit
Objectives

- To determine Egyptian research participants’:
  - Perception of the Informed Consent process
  - Understanding of research
  - Ability to distinguish between research and clinical care (therapeutic misconception).
A questionnaire was developed with the following domains:
- Demographic data
- Informed Consent Process
- Evidence of Therapeutic Misconception
- Reasons for participation

Responses were scored on a 5-point Likert Scale
Methodology

A descriptive and bivariate analysis* was used to identify responses associated with participant characteristics:

- **Age**
  - <40, 40-55, >55

- **Education**
  - Illiterate, high-school-or-less, higher-education

- **Employment**
  - Professional, manual labor, unemployed

* *Fisher’s Exact Test*

\( p < 0.05 \) was considered significant
Results

103 Egyptian patients were surveyed

- 54 were males
- Participating in 11 different clinical trials
Study participants by age

- < 40 Yrs: 27%
- 40 - 55 Yrs: 48%
- > 55 Yrs: 25%
Study participants by education

- Higher Education: 32%
- High-School-or-less: 51%
- Illiterate: 17%
Study participants by employment

- Professional: 19.5%
- Manual Labor: 42.5%
- Unemployed: 38%
91% Participants agreeing that receiving health services is not contingent on research participation, by employment

\[ p = 0.015 \]
91% Participants agreeing that receiving health services is not contingent on research participation, by education

- Higher Education: 28%
- High School or Less: 54%
- Illiterate: 18%

$p = 0.015$
Participant responses denoting misunderstanding of research method

Unaware of possibly receiving Experimental drug: 60%

Unaware of Randomization: 81%
Participant responses denoting therapeutic misconceptions

- 72% Believed that they would receive new/better drug

Pie chart showing 72% Agree and 28% Disagree.
Participants with therapeutic misconception, by education

- Higher Education: 40%
- High-school-or-less: 44%
- Illiterate: 16%

$p = 0.018$
Reasons given for participation in clinical trials

- Receive money or gifts: 5%
- Get free hospital Care: 16%
- Receive expensive / unavailable drugs: 47%
Participants expecting to get free hospital care, by education

<table>
<thead>
<tr>
<th>Education Level</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Higher Education</td>
<td>12%</td>
</tr>
<tr>
<td>high-school-or-less</td>
<td>50%</td>
</tr>
<tr>
<td>Illiterate</td>
<td>38%</td>
</tr>
</tbody>
</table>

P = 0.032
Conclusion

Our survey revealed that

- Many participants harbor misunderstandings about research participation
Recommendations

- Investigators should dedicate sufficient time to explain:
  - Research methods
  - Risks and benefits and
  - To emphasize the distinction between research and clinical care
Thank You!