

The “Personal Health Budget” intervention model in early psychosis: preliminary findings from the Parma experience

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SUMMARY

Objectives

Personal Health Budget (PHB) has recently been provided to people with severe mental illness, reflecting a policy shift towards a personalized mental health care based on individual unmet needs. However, evidence on effectiveness of PHB initiatives is still limited. Aim of this research was to provide preliminary data about the beneficial effects of adding PHB to a multicomponent EIP intervention in patients with First-Episode Psychosis (FEP) along a 2-year follow-up period.

Methods

Participants ($n = 49$) were FEP patients, aged 18-50 years, entered the “Parma Early Psychosis” program and completing the Health of Nation Outcome Scale (HoNOS), the Brief Psychiatric Rating Scale (BPRS) and the Global Assessment of Functioning (GAF). Friedman test for repeated measure (with Wilcoxon test as post-hoc procedure) was performed to evaluate the longitudinal stability of functioning and clinical parameters. A linear regression analysis was also carried out.

Results

A significant effect of time on all HoNOS, BPRS and GAF scores along the 2 years of follow-up was found. Regression analysis results specifically showed a relevant association between a PHB multiaxial intervention and the longitudinal decrease in BPRS “Negative Symptoms” subscores, as well as in HoNOS “Behavioral Problems” and “Social Problems” scores.

Conclusions

Our results support the general applicability of a PHB approach within an “Early Intervention in Psychosis” program for help-seeking adults with FEP.

Key words: personal health budget, early intervention in psychosis, first episode psychosis, early psychosis, mental health services, rehabilitation

Introduction

Welfare systems of modern Western societies have recently implemented new forms of organization and social/health integration increasingly centered on patients and their unmet needs, and structured on a local community basis¹. This paradigm shift was a consequence of providing a better service to the users, as well as more tailored interventions aimed at leading to innovative, network-based practices that integrated public

health services, patients' and their families' resources and local communities ones (such as those of social agencies, third sector and voluntary associations) ². This also translated into a reduction of intensive or residential treatments in favor of long-term care interventions at home, within the belonging community ³. In this context, *Personal Health Budget* (PHB) has been proposed as an innovative rehabilitation model that consists of funds and/or indirect resources addressing users, aimed to specifically support their individual health, social and personal needs ⁴. It is a contract following an agreed plan between the person, his family and the social/healthcare services involving in taking care, within an individualized ("person-centered") rehabilitation program implemented thanks to the all interested part cooperation ⁵.

PHB in Italy

In Italy, the welfare system has in recent years undergone radical changes, moving from an institution-based healthcare model to a community-based service model, aimed at enhancing the person's point of view, his strengths and needs to be implemented within his life context ⁶. Given these premises, some Italian public mental health departments introduced the PHB as part of the patient's "Individual Rehabilitation Plan" (IRP), in order to promote his social inclusion, in spite of the severe and chronic mental health disorder he was suffering from ⁷. Indeed, it was specifically addressed to people with Severe Mental Illness (SMI), requiring rehabilitation processes made of both social and healthcare interventions ¹. The PHB is inclusive of individual, familiar, social and healthcare resources, all gathered to prevent mental health disorders from becoming chronic and to prevent patients' isolation. It is intended to connect social and healthcare systems and was developed either to allow patients' discharge from psychiatric residential facilities or to avoid/delay patients' new residential admissions ⁸. However, over time, the PHB model has expanded its purposes and has focused specific interventions on citizens' global health rather than on patients' disease, preventing the most fragile subjects from being isolated from their native community. Indeed, PHB is intended to merge social interventions with healthcare system ones, but also with individual, familiar and environmental resources, in order to create tailor-made pathways to care, promoting and maintaining patients' social inclusion within their belonging communities ⁹. In this context, the 2015 Emilia-Romagna Regional Council Deliberation Act n.1554 ("Guidelines for the implementation of individual pathway to care through the PHB methodology application) has officially given start to the PHB model implementation in all the regional mental health departments, with specific attention to adult psychiatric services ⁷.

Starting from this background, the *aim* of this research was to provide preliminary data about the beneficial effects of adding PHB to a multicomponent EIP ("Early Intervention in Psychosis") intervention in adults with First-Episode Psychosis (FEP). Specifically, we wanted to compare clinical and functional outcome indicators across a 2-year follow-up period. Main hypothesis of the current study was that positive outcomes could be obtained – in terms of clinical recovery and socio-occupational functioning – thanks to the PHB approach application (i.e. an integrated rehabilitation treatment on the axis "housing-work-sociality") within a specific EIP protocol for FEP patients provided in all adult psychiatric services of the Parma Department of Mental Health (i.e. the "Parma Early Psychosis" [Pr-EP] program) ¹⁰, already compounding psychoeducational, pharmacological and psychotherapy interventions in patients' native environment. To the best of our knowledge, no study on PHB model in early psychosis has been published in the literature to date.

Materials and methods

Participants

Data were retrospectively collected at the baseline and at the follow-up routine assessments of help-seeking adults recruited through the Pr-EP program between January 2015 and December 2018. All participants (n = 49) agreed to participate to the study and gave their written informed consent prior to their inclusion in the research. Local ethical approval for the study was obtained (AVEN Ethics Committee: protocol n. 36102/09.09.2019). The present research has been also carried out in accordance with the Code of Ethics of the World Medical Association (Declaration of Helsinki) for experiments including humans.

For the purpose of this study, inclusion criteria were: (a) specialist help-seeking; (b) age between 18 and 50 years; (c) presence of FEP criteria within one of the following psychiatric diagnoses as defined in accordance with the Diagnostic and Statistical Manual of mental disorders, IV edition, Text Revised (DSM-IV-TR) ¹¹: schizophrenia, bipolar disorder with psychotic symptoms, major depressive disorder with psychotic symptoms, delusional disorder, brief psychotic disorder, schizophreniform disorder and psychotic disorder not otherwise specified; and (d) a Duration of Untreated Psychosis (DUP, defined as the period of treatment delay [in months] between the onset of psychotic symptoms and the first pharmacotherapy administration) ¹² < 2 years. According to the FEP criteria defined by the Italian version of the "Comprehensive Assessment of At-Risk Mental States" (CAARMS-ITA) ¹³, the threshold of a full-blown psychotic episode is defined by operationalized

clear-cut levels of overt positive symptoms occurring for > 1 week, either daily or > 3 times a week with each symptom lasting for > 1 hour on each occasion. Furthermore, we opted for a DUP cut-off of < 2 years because it is considered the limit to start a specific care protocol according to the EIP paradigm¹⁴.

Exclusion criteria were: (a) history of previous affective and non-affective psychosis, in accordance with the DSM-IV-TR criteria (DSM-IV-TR)¹¹ (b) past exposure to antipsychotics or ongoing antipsychotic treatment started more than three months before the baseline assessment (c) current substance abuse/dependence, according to the DSM-IV-TR¹¹; (d) known intellectual disability (Intelligence Quotient < 70); and (e) neurological disorders, head injury, or any other medical condition associated with psychiatric symptoms. In the Pr-EP program, we specifically considered previous exposure to antipsychotics (i.e. before the Pr-EP enrollment) as an equivalent of a past psychotic episode. Indeed, according to the FEP criteria proposed by Yung and co-workers (2005)¹⁵ in the original version of the CAARMS, the threshold of a full-blown psychotic episode is the clinical condition requiring an antipsychotic medication to be started in the common clinical practice. Furthermore, we opted for an antipsychotic treatment interval shorter than three months because of our attempt to select FEP patients at the very beginning of their pharmacological treatment.

Instruments

The psychopathological assessment for this study included the Brief Psychiatric Rating Scale (BPRS) – version 4.0¹⁶, the Global Assessment of Functioning (GAF) scale¹¹ and the Health of Nation Outcome Scale (HoNOS)¹⁷.

The BPRS – version 4.0¹⁶ – is an instrument enabling the clinician to quickly collect information about the presence/absence and the severity of 24 main psychiatric symptoms, rated on a Likert scale ranging from 1 (“not present”) to 7 (“extremely severe”). In the present study, we used the BPRS 5-factor model proposed by Dazzi and colleagues (2016)¹⁸ and including “Positive”, “Negative”, “Affect”, “Activation” and “Disorganization” dimensions. In the current research, we used the authorized Italian translation of the BPRS – version 4.0, which showed good psychometric properties in Italian clinical populations¹⁹.

The GAF is a scale used to rate patient’s social, occupational and psychological functioning. Scores range from 100 (“extremely high functioning”) to 1 (“severely impaired functioning”). In the present study, we used the Italian version of the GAF scale included in the DSM-IV-TR²⁰, already previously administered in Italian clinical populations of adolescents and adults with FEP^{21,22}.

The HoNOS was developed to measure improvements in health and social functioning of people with endur-

ing mental health problems¹⁷. Structurally, the HoNOS includes 12 items, each one rated on a 4-point Likert scale (from 0 = “no problem” to 4 = “severe to very severe problems”). A total score is obtained and subscale scores can also be calculated by combining groups of items as follows: (a) “Behavioral Problems” (items 1-3), (b) “Impairment” (items 4 and 5), (c) “Psychiatric Symptoms” (items 6-8) and (d) “Social Problems” (items 9-12)²³.

Procedures

The axis-I diagnosis was made accordingly with the DSM-IV-TR diagnostic criteria¹¹ through the Structured Clinical Interview for DSM-IV-TR axis I disorders (SCID-I)²⁴ administered by two trained Pr-EP team members^{10,25}. After the SCID-I evaluation, all the help-seekers meeting the CAARMS-defined FEP criteria¹⁵ were included in the Pr-EP program and were assigned to a multi-professional team, generally within 3 weeks from the referral. Based on severity of their symptoms, FEP patients were provided with a comprehensive 2-year intervention program including pharmacological treatment and a multi-component psychosocial intervention (combining individual cognitive-behavioral-oriented psychotherapy, psychoeducational sessions for family members and a recovery-oriented case management), according to the most recent guidelines^{26,27}. Low-dose atypical antipsychotics were prescribed as first-line treatment.

The PHB methodology was proposed as an integration of the standard Pr-EP interventions to all FEP patients with a relevant complexity on the following areas of functioning: housing, employment and/or social participation. Individuals who accepted the PHB proposal were included in the study. The PHB model is an integrated (social and healthcare) approach supporting the IRP of people with SMI and consisting in a mixture of social, health, personal and family resources. It is aimed to improve their clinical and functional recovery, as well as their social inclusion and active participation in the native community through the activation of rehabilitation programs⁸. Specifically, it may be activated to sustain home care programs, to support family care through specific interventions of supported accommodation and social/occupational empowerment, and to prevent social isolation⁷.

The qualifying elements of the PHB model were: (a) a Multidimensional Evaluation Unit (MEU), including mental health and social services, defining the IRP and the PHB resources according to the principles of appropriateness and equity; and (b) an IRP, recovery-oriented, person-tailored and based on a careful evaluation of the patient’s needs and abilities (rather than depending on the services’ offer), developed together with the user, his family members and (if appropriate) with other local

community agencies (such as social cooperatives) ⁸. In the current study, the PHB integrated the standard PR-EP protocol by providing specific interventions within the social areas most affecting people's health (i.e. housing, employment and social relationships), in order to create and maintain virtuous connections between community healthcare and social systems through an appropriate use of their resources ²⁷.

Within the "Housing" axis, interventions could include actions aimed at supporting life at home or at gaining a new home/accommodation, either individually or in co-housing groups. Depending on personal needs, different forms of support were provided, ranging from temporary, active home support (in order to strengthen the autonomy in everyday life) to more prolonged interventions for the maintenance of a good family and environmental conditions. Within the "Sociality" axis, rehabilitation treatments aimed at promoting friendship, family relationships and social networks, enhancing the patient's empowerment and/or the development of social skills. Specifically, interventions had to stimulate the participation in cultural, relational, recreational, and sport activities into the individual's living environment. Finally, the "Training/Work" intervention axis included all actions aimed at promoting social inclusion and active participation in the community through training activities and supported employment, also within the Italian legislative framework regarding apprenticeships and job placements ⁴.

PHB resources could include: (a) healthcare ones, provided by community adult mental health services, often relying on social cooperatives; (b) social resources, provided by the local social agencies for integration and social inclusion (e.g. social service professionals, educators, public housing, meals at home, financial aids); (c) patient's resources including both economic and relational ones (i.e. family members, friends); and (d) resources coming from local voluntary associations. The IRP was signed by all the involved subjects (i.e. patient, family, mental health case manager, social service professional, etc.), therefore making the individual PHB official.

Statistical analysis

Data were analyzed using the Statistical Package for Social Science (SPSS) for Windows, version 15.0 ²⁸. All tests were two-tailed. Threshold of significance was set at $p = 0.05$. Frequencies and percentages were used to describe categorical parameters, whereas mean values \pm standard deviation were used to represent continuous parameters. Due to non-normality in all explorations (i.e. Kolmogorov-Smirnov test with Lilliefors correction: $p < 0.05$) ²⁹, non-parametric statistics were used. Specifically, Friedman test for repeated measures (and Wilcoxon test with Bonferroni correction as post-hoc pro-

cedure for multiple comparisons) ³⁰ was performed to evaluate the longitudinal stability of BPRS, HoNOS and GAF scores in the FEP group across the 2-year follow-up period. Finally, linear regression analysis (with functioning and psychopathological scores as dependent variables, and PHB intervention [multi-axial vs uniaxial] as independent variable) was also performed.

Results

Over the course of the study, 49 FEP patients (36 [73.5%] males, 42 [85.7%] white Caucasians, mean age = 26.08 ± 6.29 years) were retrospectively enrolled in the research (see Table I for details on sociodemographic and clinical characteristics of the FEP total group). The sample included individuals with DSM-IV-TR schizophreniform disorder ($n = 16$; 32.6%), schizophrenia ($n = 14$; 28.6%), affective (bipolar or major depressive) psychosis ($n = 7$; 14.3%), brief psychotic disorder ($n = 6$; 12.2%), psychotic disorder not otherwise specified ($n = 4$; 8.3%), delusional disorder ($n = 1$; 2.0%) and schizoaffective disorder ($n = 1$; 2.0%). As regard the PHB intervention typology, 18 (36.7%) FEP participants received a PHB multi-axis approach. Moreover, 44 (89.8%) of FEP individuals were provided with a PHB intervention on the "Training/Work" axis, 21 (42.9%) on the "Sociality" axis and 4 (8.2%) on the "Housing" axis. All FEP patients concluded the 2-year follow-up period, with the exception of 3 (6.1%) individuals who dropped out during the second year of the study.

Follow-up data

Across the 2-year follow-up period, a statistically significant decrease in the severity of all BPRS and HoNOS scores was found (Tab. II). A relevant longitudinal improvement in GAF score was also observed. However, in the time period between T1 and T2 (i.e. between 1-year and 2-year assessment times), no further decrease in BPRS "Negative" and "Disorganization" factor subscores was reported.

Finally, linear regression analysis results showed a statistically significant negative association between multi-axial PHB intervention (as independent variable) and the difference (delta [Δ]) between T2 and T0 (baseline) BPRS "Negative" factor subscores (as dependent variable) (Tab. III). A multi-axial PHB approach also had a relevant negative association with the deltas between T2 and T0 HoNOS "Behavioral Problems" and "Social Problems" subscale scores.

Discussion

In the past two decades, empirical evidence showed that psychopharmacological treatment alone, despite clinical improvement, is not enough to prevent relapses

TABLE I. Sociodemographic and clinical characteristics of the FEP total sample (n = 49).

Variable	
Gender (males)	36 (73.5%)
Age at entry	26.08 ± 6.29
Education (in years)	11.71 ± 3.96
Ethnic group (white Caucasian)	42 (85.7%)
Mother tongue (Italian)	36 (76.5%)
DUP (in month)	9.21 ± 7.56
DSM-IV-TR diagnosis	
<i>Schizophreniform disorder</i>	16 (32.6%)
<i>Schizophrenia</i>	14 (28.6%)
<i>Brief psychotic disorder</i>	6 (12.2%)
<i>Affective psychosis</i>	7 (14.3%)
<i>Psychosis not otherwise specified</i>	4 (8.3%)
<i>Delusional disorder</i>	1 (2.0%)
<i>Schizoaffective disorder</i>	1 (2.0%)
Participants who dropped out during the 2-year follow-up period	3 (6.1%)

Legend – FEP: first episode psychosis; DUP: duration of untreated psychosis; DSM-IV-TR: Diagnostic and statistical manual of mental disorders, 4th Ed., Text Revised. Frequencies (percentages) and mean ± standard deviation are reported.

TABLE II. Functioning and psychopathological characteristics across the 2-year follow-up period in the FEP total sample (n = 49).

Variable	T0	T1	T2	F _[2]	Post-hoc [†]
BPRS scores					
<i>BPRS “affective”</i>	14.53 ± 5.22	10.81 ± 3.80	9.09 ± 2.59	55.04 [*]	T0 > T1 > T2
<i>BPRS “positive”</i>	16.85 ± 5.64	11.02 ± 4.46	9.50 ± 3.57	55.11 [*]	T0 > T1 > T2
<i>BPRS “activation”</i>	12.56 ± 6.25	8.58 ± 3.50	7.52 ± 2.32	52.92 [*]	T0 > T1 > T2
<i>BPRS “negative”</i>	8.67 ± 3.32	6.46 ± 2.51	7.31 ± 2.07	31.49 [*]	T0 > T1 = T2
<i>BPRS “disorganization”</i>	9.19 ± 3.84	6.49 ± 2.62	7.04 ± 2.51	45.42 [*]	T0 > T1 = T2
<i>BPRS total score</i>	66.38 ± 17.98	47.47 ± 12.43	43.83 ± 10.13	55.96 [*]	T0 > T1 > T2
HoNOS scores					
<i>“Behavioral problems”</i>	3.49 ± 2.74	1.77 ± 2.01	0.83 ± 0.96	55.77 [*]	T0 > T1 > T2
<i>“Impairment”</i>	2.83 ± 2.01	1.98 ± 1.58	1.60 ± 1.36	29.44 [*]	T0 > T1 > T2
<i>“Psychiatric symptoms”</i>	10.04 ± 3.37	5.85 ± 2.81	4.06 ± 2.34	83.37 [*]	T0 > T1 > T2
<i>“Social problems”</i>	8.00 ± 2.83	5.85 ± 2.79	4.50 ± 2.51	66.94 [*]	T0 > T1 > T2
<i>HoNOS total score</i>	29.87 ± 11.26	18.29 ± 9.15	11.16 ± 5.05	54.05 [*]	T0 > T1 > T2
GAF score	44.02 ± 13.14	58.39 ± 11.81	64.48 ± 11.96	90.04	T0 < T1 < T2

Legend – FEP: first episode psychosis, BRPS: Brief Psychiatric Rating Scale; HoNOS: Health of Nation Outcome Scale; GAF: global assessment of functioning; T0: baseline assessment; T1: 1-year assessment time; T2: 2-year assessment time; [df]: [degrees of freedom]. Mean ± standard deviation and Friedman test (χ^2) value are reported. Wilcoxon test with Bonferroni correction was used as post-hoc procedure for multiple comparisons. ^{*}p < 0.001; [†]Bonferroni corrected p value < 0.0167.

or to ensure a stable functional recovery in people with FEP both in the medium and the long term³¹⁻³³. With reference to this, recent systematic reviews suggested that integrated psychosocial interventions (together with pharmacological therapy) in FEP patients are more effective in reducing inpatient care, treatment drop-out, morbidity and related disability, as well as in improving

long-term clinical and functional outcomes, and in combining a symptom reduction/remission with a relevant improvement in terms of quality of life, social and cognitive functioning and less frequent self-injurious behaviors³⁴⁻³⁸.

In the EIP paradigm context, the PHB model may therefore represent an innovative, integrated psychosocial

TABLE III. Linear regression analysis results by multi-axis PHB intervention (independent variable) on functioning and psychopathological scores along the 2-year follow-up period (dependent variables) in the FEP total group (n = 49).

T2-T0 Delta BPRS “affective” factor subscore	B	SE	β	p	95% CI for B	
					Lower	Upper
Constant	-3.137	2.087	-	0.140	-7.342	1.067
Multi-axis PHB intervention	-1.696	1.446	-0.172	0.247	-4.608	1.215
Model summary: R ² = 0.030; F = 1.377; p = 0.247						
T2-T0 Delta BPRS “positive” factor subscore	B	SE	β	p	95% CI for B	
					Lower	Upper
Constant	-5.013	2.553	-	0.056	-10.152	0.126
Multi-axis PHB intervention	-1.729	1.778	-0.142	0.336	-5.307	1.850
Model summary: R ² = 0.020; F = 0.946; p = 0.336						
T2-T0 Delta BPRS “activation” factor subscore	B	SE	β	p	95% CI for B	
					Lower	Upper
Constant	-3.279	2.688	-	0.229	-8.690	2.132
Multi-axis PHB intervention	-1.302	1.872	-0.102	0.490	-5.069	2.466
Model summary: R ² = 0.010; F = 0.484; p = 0.490						
T2-T0 Delta BPRS “negative” factor subscore	B	SE	β	p	95% CI for B	
					Lower	Upper
Constant	1.480	1.180	-	0.216	-0.895	3.855
Multi-axis PHB intervention	-2.093	0.822	-0.352	0.014	-3.747	-0.439
Model summary: R ² = 0.124; F = 6.490; p = 0.014						
T2-T0 Delta BPRS “disorganization” factor subscore	B	SE	β	p	95% CI for B	
					Lower	Upper
Constant	0.102	0.628	-	0.872	-1.163	1.367
Multi-axis PHB intervention	0.331	0.435	0.113	0.450	-0.545	1.208
Model summary: R ² = 0.013; F = 0.580; p = 0.450						
T2-T0 Delta HoNOS “behavioral problems” subscale subscore	B	SE	β	p	95% CI for B	
					Lower	Upper
Constant	-0.444	1.043	-	0.673	-2.545	1.658
Multi-axis PHB intervention	-1.653	0.734	-0.318	0.029	-3.131	-0.175
Model summary: R ² = 0.101; F = 5.076; p = 0.029						
T2-T0 Delta HoNOS “impairment” subscale subscore	B	SE	β	p	95% CI for B	
					Lower	Upper
Constant	-1.340	0.773	-	0.090	-2.896	0.217
Multi-axis PHB intervention	0.082	0.538	0.022	0.880	-1.002	1.165
Model summary: R ² = 0.022; F = 0.023; p = 0.880						
T2-T0 Delta HoNOS “psychiatric symptoms” subscale subscore	B	SE	β	p	95% CI for B	
					Lower	Upper
Constant	-4.332	1.210	-	0.001	-6.768	-1.896
Multi-axis PHB intervention	-1.216	0.843	-0.208	0.156	-2.913	0.480
Model summary: R ² = 0.043; F = 2.083; p = 0.156						
T2-T0 Delta HoNOS “Social problems” subscale subscore	B	SE	β	p	95% CI for B	
					Lower	Upper
Constant	-0.552	0.968	-	0.571	-2.501	1.396
Multi-axis PHB intervention	-2.286	0.681	-0.448	0.002	-3.657	-0.916
Model summary: R ² = 0.201; F = 11.286; p = 0.002						
T2-T0 Delta GAF score	B	SE	β	p	95% CI for B	
					Lower	Upper
Constant	18.953	6.254	-	0.004	6.363	31.542
Multi-axis PHB intervention	1.112	4.355	0.038	0.800	-7.654	9.878
Model summary: R ² = 0.001; F = 0.065; p = 0.800						

Legend – PHB: personal health budget; FEP: first episode psychosis; T2: 2-year assessment time; T0: baseline assessment; T2-T0 Delta: difference between T2 and T0 scores; BPRS: Brief Psychiatric Rating Scale; HoNOS: Health of Nation Outcome Scale; GAF: Global Assessment of Functioning; B: unstandardized regression coefficient; SE: Standard Error; β : standardized regression coefficient; p: statistical significance; 95% CI: 95% confidence intervals; R²: R square; F: F test value. Statistically significant p values are in bold.

approach aimed at an effective social and healthcare integration, placing the person in his life environment and giving him an active role in the co-planning of his life project⁴. Indeed, PHB has been proposed as a new design of assistance resulting in a promotion of individuals instead of certain services or service institutions³⁹, as a way for personalizing care based around what matters to people and their personal strengths and needs^{7,40}. Thus, the PHB model becomes feasible only within an effective *social-health integration*, aimed at creating a continuity of care for patients whose health is compromised and rebuilt in the daily life of their existence⁴. Within this conceptual framework, the main aim of the present research was to provide preliminary data about the beneficial effects of adding PHB to a specialized EIP multicomponent intervention (i.e. the Pr-EP program)^{10,25}.

Follow-up data

The results of the current study showed a significant improvement on functioning and on all the examined psychopathological and outcome variables (i.e. BPRS and HoNOS scores) in the FEP total group across the 2 years of follow-up. This confirms an overall effectiveness of a specialized EIP program (i.e. the Pr-EP protocol) in improving clinical and functional recovery of FEP patients, and supports promising add-on benefits of PHB interventions on “Sociality”, “Training/Work” and “Housing” axes, also within the Italian public mental health network^{22,25,41}. However, within a continuous and progressive reduction in psychopathology severity, the improvement in negative symptoms and disorganization appears to be more relevant during the first year of intervention. These findings support the great therapeutic effort required by negative and disorganized dimensions of psychosis^{42,43}, already at the onset of illness^{14,21}.

Linear regression analysis results also showed that a PHB multi-axial approach significantly predicted a specific improvement in negative symptoms and in behavioral and social problems of FEP patients after 2 years of follow-up. This supports findings reported in other studies on PHB approach conducted in the UK and in the Netherlands^{40,44-46}, suggesting a positive impact of PHB interventions on psychological well-being in patients with SMI. Specifically, in these studies outcomes mainly included decreased severity in psychopathology, a better daily functioning, improved relationships and reduced drug misuse. The success of PHB model has been attributed to both a “flexibility through partnership” (creating a policy framework to enable decisions about how many resources each person should get within a cash-limited budget) and a “self-directed support” (based on the individual being given a budget with which to plan his own care)⁴⁵. In this context, it is

crucial for the individuals (particularly those with problems that already restrict their ability to live the life they want) to have autonomy in choosing their own care. Indeed, PHB should not be considered as new money, but as a different way of spending social/health funds in order to meet specific personal needs⁴⁶.

Limitations

Some limitations of the study should be acknowledged. First, this research was a descriptive, retrospective cohort study with no control group. Thus, a longitudinal case-control research is needed in order to better examine the PHB effectiveness.

Second, FEP participants provided with PHB intervention voluntarily accepted the PHB proposal. Thus, randomized controlled trials on effects and outcomes of PHB model are needed.

Third, in the present retrospective research the follow-up duration was limited to 24 months. Therefore, our findings should be replicated in longer-term perspective studies.

Another weakness was also the relatively limited sample size of the FEP group. This probably reduces the generalizability of our findings, which should be replicated in larger clinical samples.

Finally, in the current study we considered a wide age range (18-50 years) as an inclusion criterion. Thus, our findings should be replicated in more uniform age groups, such as in clinical populations of FEP adolescent and young adult help-seekers.

Conclusions

The results of the current research overall support the general effectiveness of a specialized EIP intervention and the add-on benefits of PHB to a specialized EIP protocol in terms of improving functioning and decreasing psychopathology severity in help-seekers with FEP across a 2-year follow-up period. Indeed, this improvement (especially in negative symptoms and in behavioral and social problems) appears to be further enhanced by a PHB approach, based on the integration of professional knowledge and technical skills in order to provide person-tailored social/healthcare pathways within a community care system⁴. In other words, the implementation of PHB in Italian public mental health services has no detrimental effect to people in treatment, does not seem to be in conflict with a multicomponent EIP program and suggests that it may be effective in addressing the hot issue of social retirement and unmet social needs⁴⁶.

In this regard, the England National Health Service (NHS) suggested that subjects who are eligible for a PHB, are individuals “having a medical illness that requires a highly specialized healthcare support”⁴². Since

2009, the England NHS implemented PHBs for patients with SMI and for children and adolescents in residential care, aiming at encouraging innovative rehabilitation approaches to effectively improve well-being outcomes³⁸.

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References

- De Vivo C, Ascani M, Cacciola S. Il budget di salute come nuovo strumento di welfare. *Eyes Reg* 2019;9:1.
- Maino F. L'innovazione sociale nell'Unione Europea: uno stimolo per il rinnovamento del welfare. *Quad Economia Soc* 2014;1:10-5.
- Exworthy M, Powell M, Glasby J. The governance of integrated health and social care in England since 2010: great expectations not met once again? *Health Policy* 2017;121:1124-30.
- Pellegrini P, Ceroni P, Dall'Aglio R, et al. *Soggetto, persona, cittadino: budget di salute in Emilia-Romagna*. Merano (BZ): Edizioni alpha beta Verlag 2019.
- Wirrmann Gadsby E. *Personal budgets and health: a review of the evidence*. Kent: Centre for Health Services Studies, University of Kent 2013.
- Starace F. *Manuale pratico per l'integrazione socio-sanitaria: il modello del budget di salute*. Roma: Carocci Faber 2011.
- Pellegrini P, Ceroni P, Cocconi R, et al. *La collettività per la collettività*. Bologna: Centro stampa della Regione Emilia-Romagna 2015.
- Regione Emilia Romagna. *Linee di indirizzo per la realizzazione di progetti con la metodologia budget di salute*. Bologna: Centro Stampa della Regione Emilia-Romagna 2016.
- Righetti A. *Il budget di salute e il welfare di comunità: metodi e pratiche*. Bari: Laterza, 2011.
- Leuci E, Quattrone E, Pellegrini P, et al. The “Parma-Early Psychosis” program: general description and process analysis after 5 years of clinical activity. *Early Interv Psychiatry* 2019;Nov 22. <https://doi.org/10.1111/eip.12897>
- American Psychiatric Association (APA). *Diagnostic and statistical manual of mental disorders, 4th Ed., Text Revised*. Washington DC: APA Press 2000.
- Ran MS, Xiao Y, Chui CHK, et al. Duration of untreated psychosis (DUP) and outcome of people with schizophrenia in rural China: 14-year follow-up study. *Psychiatry Res* 2018;267:340-5.
- Pelizza L, Paterlini F, Azzali S, et al. The approved Italian version of the comprehensive assessment of at-risk mental states (CAARMS-ITA): field test and psychometric features. *Early Interv Psychiatry* 2019;13:810-7.
- Poletti M, Pelizza L, Azzali S, et al. Clinical high risk for psychosis in childhood and adolescence: findings from the 2-year follow-up of the ReARMS project. *Eur Child Adolesc Psychiatry* 2019;28:957-71.
- Yung AR, Yuen HP, McGorry PD, et al. Mapping the onset of psychosis: the Comprehensive Assessment of At-Risk Mental States. *Aust N Z J Psychiatry* 2005;39:964-71.
- Ventura J, Green M, Shaner A, et al. Training and quality assurance with the Brief Psychiatric Rating Scale: “The drift busters”. *Int J Methods Psychiatr Res* 1993;3:221-44.
- Wing JK, Beevor AS, Curtis RH, et al. Health of the Nation Outcome Scales (HoNOS): research and development. *Br J Psychiatry* 1998;172:11-8.
- Dazzi F, Shafer A, Lauriola M. Meta-analysis of the Brief Psychiatric Rating Scale – expanded (BPRS-E) structure and arguments for a new version. *J Psychiatr Res* 2016;81:140-51.
- Roncione R, Ventura J, Impallomeni M, et al. Reliability of an Italian standardized and expanded Brief Psychiatric Rating Scale (BPRS 4.0) in raters with high vs low clinical experience. *Acta Psychiatr Scand* 1999;100:229-36.
- Andreoli V, Cassano GB, Rossi R. *DSM-IV: Manuale diagnostico e statistico dei disturbi mentali, 4th Ed., Text Revision*. Milano: Masson 2007.
- Pelizza L, Azzali S, Garlassi S, et al. Adolescents at ultra-high risk of psychosis in Italian neuropsychiatry services: prevalence, psychopathology and transition rate. *Eur Child Adolesc Psychiatry* 2018;27:725-37.
- Ferrara M, Tedeschini E, Baccari F, et al. Early intervention service for first episode psychosis in Modena, Northern Italy: the first hundred cases. *Early Interv Psychiatry* 2019;13:1011-7.
- Gale TM, Boland B. A model for predicting missing items on the Health of the Nation Outcome Scale (HoNOS). *Compr Psychiatry* 2019;93:61-4.
- First MB, Spitzer RL, Gibbon M, et al. *Structured clinical interview for DSM-IV-TR Axis I disorders (SCID-I)*. New York, NY: New York State Psychiatric Institute 2002.
- Leuci E, Damini C, Ceroni P, et al. *PDTA aziendale “Esordi Psicotici”*. Parma: Centro Stampa dell'AUSL di Parma 2019.
- National Institute for Health and Care Excellence (NICE). *Psychosis and schizophrenia in children and young people: recognition and management*. Leicester: British Psychological Society 2013.
- Regione Emilia Romagna: *Raccomandazioni regionali per la promozione della salute e del benessere in persone all'esordio psicotico*. Bologna, Centro stampa della Regione Emilia Romagna 2016.
- SPSS Inc. *Statistical Package for Social Science (SPSS) for Windows, version 15.0*. Chicago (IL): SPSS Inc. Press 2010.
- Gravetter F, Wallnau L. *Essentials of statistics for the behavioral sciences, 8th Ed*. Belmont, CA: Wadsworth 2014.
- Field A. *Discovering statistics using SPSS, 4th Ed*. London: Sage 2013.
- Bird V, Premkumar P, Kendall T, et al. Early intervention services, cognitive-behavioral therapy and family intervention in early psychosis: systematic review. *Br J Psychiatry* 2010;197:350-6.
- Behan C, Kennelly B, Roche E, et al. Early intervention in psychosis: health economic evaluation using the net benefit

- approach in a real-world setting. *Br J Psychiatry* 2019;Jul 24. <https://doi.org/10.1192/bjp.2019.126>
- ³³ Montemagni C, Rocca P. Assessing cognition and real-world functioning in schizophrenia. *Journal of Psychopathology* 2018;24:49-5.
- ³⁴ Albert N, Weibell MA. The outcome of early intervention in first episode psychosis. *Int Rev Psychiatry* 2019;31:413-24.
- ³⁵ Chan SKW, Chan HYV, Devlin J, et al. A systematic review of long-term outcomes of patients with psychosis who received early intervention services. *Int Rev Psychiatry* 2019;31:425-40.
- ³⁶ Pelizza L, Azzali S, Paterlini F, et al. The “Reggio Emilia At-Risk Mental States” program: a diffused, “liquid” model of early intervention in psychosis implemented in an Italian Department of Mental Health. *Early Interv Psychiatry* 2019;13:1513-24.
- ³⁷ Pelizza L, Poletti M, Azzali S, et al. Suicidal thinking and behavior in adolescents at Ultra-High Risk of psychosis: a two-year longitudinal study. *Suicide Life Threat Behav* 2019;49:1637-52.
- ³⁸ Corrivetti G, Caserta D, Perna C. Implementation of cognitive rehabilitation in psychiatric services: Integration of cognitive remediation and psychosocial rehabilitation. *Journal of Psychopathology* 2018;24:93-7.
- ³⁹ Wacker E. The personal budget: a new system of benefits for disabled people. *Rehabilitation (Stuttg)* 2009;48:4-14.
- ⁴⁰ Oliver D. What’s the verdict on personal health budgets? *BMJ* 2019;366:5138.
- ⁴¹ Pelizza L, Ficarelli ML, Vignali E, et al. Individual placement and support in Italian young adults with mental disorder: findings from the Reggio Emilia experience. *Early Interv Psychiatry* 2019;Oct 23. <https://doi.org/10.1111/eip.12883>
- ⁴² Galderisi S, Mucci A, Buchanan RW, et al. Negative symptoms of schizophrenia: new developments and unanswered research questions. *Lancet Psychiatry* 2018;5:664-77.
- ⁴³ Vignapiano A, Koenig T, Mucci A, et al. Disorganization and cognitive impairment in schizophrenia: new insight from electrophysiological findings. *Int J Psychophysiol* 2019;145:99-108.
- ⁴⁴ Vogel L. Dance lessons on a personal health budget. *CMAJ* 2012;184:444-6.
- ⁴⁵ Davidson J, Baxter K, Glendinning C, et al. Choosing health: qualitative evidence from the experiences of personal health budget holders. *J Health Serv Res Policy* 2013;18 (Suppl 2):50-8.
- ⁴⁶ Tompkins CNE, Parkman T, Potheary JC. Implementing and delivering personalized budgets for drug and alcohol users: a narrative systematic review. *Health Soc Care Community* 2018;27:68-81.
- ⁴⁷ Slasberg C, Watson N, Beresford P, et al. Personalization of health care in England: have the wrong lessons been drawn from the personal health budget pilots? *J Health Serv Res Policy* 2014;19:183-8.
- ⁴⁸ Pelizza L, Azzali S, Paterlini F, et al. Characterization of young people with first episode psychosis or at ultra-high risk: the Reggio Emilia At-Risk Mental States (ReARMS) program. *Riv Psichiatr* 2019;54:254-63.